PHARMADOCX

Consultant For Setting up of Manufacturing Units of Medical Devices & Import of Medical Devices

Notified Medical Devices E-Book Edition-04 UP TO 25-10-2023

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PHARMADOCX CONSULTANTS

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MEDICAL DEVICE LICENSE ON MD-5, MD-9 & MD-15 CE, ISO-13485

PHARMADOCX

DO YOU WANT TO SET UP MEDICAL DEVICE FACTORY?

PHARMADOCX

YASHDEEP DAHIYA
(C.E.O.)
Consultant for Plant Setup & Licensing Cosmetics Medical Device, Pharma, Units

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COMPANY PROFILE

Established in 2007, Pharmadocx provides consultation services to get License for Manufacturing of Medical Devices on Form MD-5, MD-9 & Import License on MD-15. We have so far setup more than 100 Medical Devices Plants & got them MD license.

Plant Setup Services- We design premises as per clients product capacity needs. We provide Civil Architectural plans, Clean Room Plan of ISO Class 7, HVAC Plan, Plumbing Plan, Electrical Plan, Equipment Plan. We design the facility as per MDR Rules 2017, US-FDA21CFR Part 820, CE Guidelines. We design the facilities for efficient working with requisite cleanliness levels.

Regulatory Services: Pharmadocx Consultant has qualified and experienced team for regulatory work for grant of all types of Medical Device Licenses. We provide time bound services.

Certification: To register your company in overseas market and also for doing good in business, your Plant must be certified by regulatory bodies. We provide consultation

LIST OF CLIENTS

AboneSurgicals Private Limited, Bengaluru
Adarsh Surgical, Ghaziabad
Alpine Biomedicals Pvt. Ltd., Ambala
Anondita Healthcare, Noida, U.P
Apothecaries Sundries Manufacturing Co.
Ariette Healthcare & Diagnostics, Delhi
Ashish & Company, Sonipat
Ask Surgical and Rehabilitation, Delhi
Atlas Surgical, Delhi
Auxein Medical Pvt. Ltd., Sonipat
Bone Life Surical, Loni, U.P
Crystal Diagnostics, Raipur
Dostan Surgical Engg. Works, Ghaziabad, U.P
Euro Medi Tools Pvt. Ltd. Delhi
Genius Ortho, UP
GB Alliance, Ludhiana
Giaplus Medical Pvt. Ltd., Mohali, Punjab
G.R. Bioure Surgical System Pvt. Ltd., U.P
Hind Health Product Private Limited, Delhi
Hospital Equipment Pvt. Ltd., Noida, U.P
J Mitra & Bros, Haryana
JR Surgical, UP
JVM Thermometer Delhi
Kute Wellness Inc., Bawana, Delhi
Microtrol Sterilazation Services Pvt. Ltd.
MNP Meditech Private Limited, Haryana
Navoiy Oftal Uzbekistan
Olympic Pharmacare Pvt. Ltd., Noida, U.P
Prasaditi Medical Equipments
Passim Lifesciences Limited, Haryana
Pivot Fabrique, Mohali, Punjab
Precision Guidetech, Noida, U.P
PR FlexmakePvt Ltd, Vadodara
Qumed Biotek Pvt Ltd, Gurugram
Rishabh Texco Private Limited, Bhilwara
Sara Healthcare, Delhi
Shagun Cares Inc, New Delhi
Super Medicare, Sonipat
Shi Mediwear Pvt. Ltd, Delhi
S R Surgicals, Haridwar
Unique Surgicals, Delhi
Zavi Medicare LLP, Jabalpur

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Document	S. No.	Proprietorship	Partnership	Directorship
Residence Proof	1a	Aadhar Card	Aadhar Card of Responsible Partner	Aadhar Card of Responsible Director
Constitution Proof	2a	GST Certificate	GST Certificate	CIN, MOA AOA
	2b			DIR-1 In case of change in director
Digital Signature	Need Digital signature of Authorized signatory.			
Premises Ownership proof	3a	Registry or Conveyance Deed		
	3b	Lease permission if applicable		
	3c	Registered rent agreement		
	3d	Electricity Bill		
Documents of Manufacturing Chemist (B. Tech, B. Sc, B. Pharma with 2 years of Exp.)	4a	Aadhar Card		
	4b	Pan Card		
	4c	10th Class Marksheet		
	4d	12th Class Marksheet		
	4e	All Years Marks Card		
	4f	College Degree		
	4g	Minimum 2 years' experience certificate		
Documents of Testing Chemist (B. Tech, B. Sc, B. Pharma with 2 years of Exp.)	4a	Aadhar Card		
	4b	Pan Card		
	4c	10th Class Marksheet		
	4d	12th Class Marksheet		

Address:
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	4e	All Years Marks Card
	4f	College Degree
	4g	Minimum 2 years' experience certificate
List of Products	5a	List of products in the format provided by us (PDX.T.003.00)
No Objection Certificates	6a	Fire NOC
	6b	Pollution NOC
Layout	7a	Blueprint of the premises
Certificates	8a	ISO 13485 from an IAF body with audit report.
Machine Details	9a	List of Machines of production and Lab
Product Test Reports	10a	Raw Material Test Reports
	10b	Finished goods test reports
	10c	Stability studies (If applicable)
	10d	Biocompatibility Reports (If Applicable)
Device Master File	11a	Device Master File as per Medical Device Rules, 2017 OR Details in format we provide (PDX.T.016.00)
Plant Master File	12a	Plant Master File as per Medical Device Rules, 2017 OR Details in format we provide (PDX.T.017.00)
If ETO Sterilizing facility at premises	13a	ETO Validation Report as per ISO 11135 including EO Residual Test.
Trademark Certificate	14a	Trademark Certificate under your name

Document	S. No.	Proprietorship	Partnership	Directorship
Documents required from Authorized Agent (Indian Company) (Importer)				
Constitution Details	1a	GST Certificate	GST Certificate	MOA & AOA
	1b			Certificate of Incorporation
	1c			DIR-1 In case of change of director
Wholesale License already held	2a	License on any 1 of the following Form 20B, 21B **OR** MD42 **OR** MD5/MD/9		
Documents required from Exporting Company (Foreign Company) (Exporter)(Original Manufacturer)				
Certificates	3a	Manufacturing License		
	3b	Free Sale Certificate		
	3c	ISO 13485:2016		
	3d	CE Certificate		
	3e	CE Design Certificate		
	3f	Declaration of Conformity		
Audit Report	4a	Audit report of the premises		
Device Master File	5a	Device Master File as per Medical Device Rules, 2017		
Plant Master File	6a	Plant Master File as per Medical Device Rules, 2017		

GOVERNMENT FEE DETAILS

Fee Details as per Medical Device Rules, 2017					
MD/IVD	**Medical Devices**			**In-Vitro Diagnostics**	
Risk Class	**CLASS A**	**CLASS B**	**CLASS C&D**	**CLASS A & B**	**CLASS C & D**
Per Site	1000$	2000$	3000$	1000$	3000$
Per Product	50$	1000$	1500$	10$	500$

Address:

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Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No: 29/Misc./3/2017-DC(292) **Date:** 01 NOV 2017

Subject: Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017 - Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices and *in vitro* diagnostic medical devices, Appendix -1, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices and in vitro diagnostic medical devices placed at Annexure-1 is subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. The component and accessories to a medical device or companion *in vitro* diagnostic medical devices has been classified separately.
3. It is also recognised that some of the medical devices or *in vitro* diagnostic medical devices may have dual use and they may be classified accordingly.
4. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. G. N. Singh)
Drugs Controller General (India)

To,

1. All Stake holders.
2. CDSCO Website.
3. Guard File.

Notice

File No. 29/Misc/3/2018-DC(18) **Date: 16.08.2018**

In continuation to the earlier Notice vide File No: 29/Misc./3/2017-DC(292) dated 01.11.2017 and amended classification list dated 06.06.2018 regarding Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017, the following Medical Devices have been added in the annexure I :

S. No.	Notified Category	Device name	General Intended Use	Risk Class
1.	Surgical Dressings	Suture Anchor (Spartan PEEK Suture Implant)	Soft Tissue Repair	C
2.	Disposable Hypodermic Needles	Special bevelled needles for implantable vascular access system	Power - injectable safety non-coring needle is a device intended for insertion into the septum of a subcutaneously implanted port for the infusion of fluids and drugs, as well as blood sampling through the port. It is manually activated during needle removal, and is designed to aid in the prevention of accidental needle-sticks. When used with ports that are indicated for power injection of contrast media into the central venous system, the needle is also indicated for power injection of contrast media.	C
3.	Internal Prosthetic Replacements	Auditory Brainstem Implant System	An auditory brain stem implant is a small device that is surgically implanted in the brain of a deaf person whose auditory nerves is lacking or damaged. The auditory nerves conduct the sound signals from the ear to the brain. The implant enables otherwise the deaf people to have a sensation of hearing.	D
4.	Surgical Dressings	Sternal fixation Reconstructive implant	Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.	C
5.	Internal Prosthetic Replacements	Dural Graft Implant	Dural Graft Implant is intended for use in procedures where the repair or	C

			substitution of the patient's dura mater is needed.	
6.	Catheters	Implantable infusion pumps with Catheters	Intended to treat chronic pain and spasticity patients. The pump is inserted below the ribs and it designed to continually transport medication to the site of action. Doses are accurate, user friendly and the device does not restrict movement.	D
7.	Catheters	Laser Sheath	Intended for use as adjuncts to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation	C
8.	Internal Prosthetic Replacements	Gluteus implants	Implant for augmentation of buttocks	C
9.	Internal Prosthetic Replacements	Calf implants	Implant for augmentation of Calf	C
10.	Blood Bags	Blood bags without anticoagulant	It is indicated for the collection of human blood and the preservation of blood components.	C
11.	Blood Bags	Blood bags with anticoagulant	It is indicated for the collection of human blood and the preservation of blood components.	C
12.	Catheters	Trocars	A trocar is made up of an obturator (which may be a metal or plastic sharpened or non-bladed tip), a cannula(basically a hollow tube), and a seal. The trocar functions as a portal for the subsequent placement of other instruments, such as graspers, scissors, staplers, etc. It is also intended to remove air or fluid for the pleural space in a closed, one way fashion.	B
13.	Catheters	Ureteral stent	Indicated to relieve obstructions in variety of benign, malignant and post-traumatic condition in the ureter. These conditions include stones and/or stone fragments or other Ureteral obstructions such as those associated with ureteral strictures, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma or in association with the Extracoporeal Shock wave	C

			lithotripsy (ESWL). The stent may be placed using endoscopic or percutaneously using standard or radiographic technique.	
14.	Heart Valves	Transcatheter Heart Valve	It is intended for people with symptomatic aortic stenosis who are considered an intermediate or high risk patient for standard valve replacement surgery.	D
15.	Surgical Dressings	Liquid bandage	Prevention of injection by limiting exposure to dirt and germs in case of minor cuts, abrasions and blisters.	B
16.	Disposable Perfusion Sets	Hemoconcentrator set	A hemoconcentrator is a fluid removal device used during cardio bypass surgery. The device is inserted into the extracorpeal circuit where it acts to control hemodilution, maintain hematocrit levels and reduce the need for additional blood products during and after surgery.	C
17.	Disposable Perfusion Sets	Apheresis Kit	Intended for the collection and separation of blood components	C
18.	Disposable Perfusion Sets	Blood Filter System	Intended for collection and preparation of various blood components	C
19.	Internal Prosthetic Replacements	Injectable implant for the treatment of vesicoureteral reflux	Treatment of vesicoureteral reflux	C
20.	Surgical Dressings	Bone wax/Haemostat	To stop bleeding at bones in orthopaedics and traumatology, thoracic surgery, dental, oral jaw surgery, neurosurgery.	C
21.	Disposable Hypodermic Syringes	Hyaluronic acid (cross linked) Pre-filled syringe	For intradermal implantation and facial soft tissue augmentation.	C
22.	Disposable Hypodermic Syringes	Crosslinked sodium hyaluronate	It is indicated as viscoelastic supplement or a replacement for synovial fluid in human joints. It is suited for treatment of symptoms of human joint dysfunctions such as osteoarthritis. The actions of the product are lubrication and mechanical support.	C
23.	Disposable Hypodermic Syringes	Hyaluronic acid with Lidocaine (cross linked) Pre-filled syringe	It is indicated for the treatment of fine lines and medium sized skin depressions and correcting infraorbital skin depressions via deep injection	C

24.	Disposable Perfusion Sets	Heat and moisture exchange/filter	It is intended to use for airway management by anaesthesia/respiratory care department.	B
25.	Catheters	Balloon dilators for Gastroenterology	Used to dilate strictures of the gastrointestinal tract, including strictures of the esophagus, pylorus, duodenum and colon.	C
26.	Internal Prosthetic Replacements	Hernia mesh	Indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.	C
27.	Disposable Hypodermic Needles	Dental needles	Dental needles are used to deliver local anaesthetic to the operative site in order to make a patient as comfortable as possible.	B
28.	Disposable Hypodermic Needles	Spinal Needles	Used for diagnostic sampling of cerebrospinal fluid, delivering anesthetics and for the introduction of contrast medium	B
29.	Disposable Hypodermic Syringes	Ophthalmic Viscosurgical Device	Viscoelastic solution for Intraocular use during eye surgery.	C
30.	Catheters	Negative pressure wound therapy bandage	Intended to generate negative pressure or suction to remove wound exudates , infection materials and tissue debris from the wound bed which may promote wound healing.	C
31.	Ablation Devices	Needle Electrode	The needle electrode family is intended to be used in conjunction with the RF generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.	C
32.	Ablation Devices	Radio Frequency (RF) Generator	Intended for general use in electrosurgical coagulation of tissue.	C
33.	Surgical dressings	Absorbent Cotton wool	It is intended to used for applying medication to, or absorbing small amounts of body fluids	A

Notice

File No. 29/Misc/3/2018-DC(85) **Date: 06.06.2018**

In continuation to the earlier Notice vide File No: 29/Misc./3/2017-DC(292) dated 01.11.2017 regarding Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017, the Annexure-1 is hereby revised for the following changes:

1. Deletion of S.N. 333 i.e. Sterile Drapes.
2. Revision of risk class of following products:

S.N.	Product Name	Earlier Risk Classification	Revised Risk Classification
256	Intra Osseous Fixation Wire	Class B	Class C
259	Bone Wire	Class B	Class C
260	Bone Cap	Class B	Class C
321	Plates, Clippers, Screws	Class B	Class C

***

Annexure 1
(Amended as on 06.06.2018)

LIST OF MEDICAL DEVICES AND IN VITRO DIAGNOSTICS ALONG WITH THEIR RISK CLASS AS PER THE PROVISIONS OF RULE 4 OF THE MEDICAL DEVICES RULES 2017

(A) List of Medical Devices under provisions of sub-rule (1) rule 4 of the Medical Devices Rules, 2017

#	Notified Device Category/Drug	Device Name	Risk Class	General Intended Use
1.	Ablation Device	Vein Ablation Device	Class C	It is a non-thermal, minimally-invasive choice for treating the source of varicose veins, providing patients with immediate recovery and a return to normal daily routines
2.	Ablation Device	Thermal Ablation Device	Class C	Destruction of tissue by application of heat. Ablation of the endometrium as a treatment for menorrhagia is performed by placing a balloon filled with hot water in the uterine cavity.
3.	Ablation Device	Radiofrequency Ablation Device	Class D	A medical procedure in which part of the electrical conduction system of the heart, tumour or other dysfunctional tissue is ablated using the heat generated from high frequency alternating current
4.	Ablation Device	Percutaneous Conduction Tissue Ablation	Class D	Clinical applications using hollow needles (cryoprobes) through which cooled, thermally conductive, fluids are circulated.
5.	Ablation Device	Suction Ablation Catheter System	Class D	Intended for use in inactivating portions of the heart's conduction system to prevent abnormal heartbeat rates, comprises a tubular body having an open, distal end and a proximal aperture for applying suction through the catheter and through the distal end.

6.	Ablation Device	Uterine balloon therapy devices	Class C	System is a closed-cycle cryosurgical device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.
7.	Ablation Device	RF Conducte MR steerable electrode catheter	Class C	It is intended for intracardiac ablation.
8.	Bone Cements	Bone cement	Class C	Intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.
9.	Cardiac Stents	Coronary stent	Class D	A coronary stent is a tube-shaped device placed in the coronary arteries that supply blood to the heart, to keep the arteries open in the treatment of coronary heart disease.
10.	Cardiac Stents	Bioresorbable Vascular Scaffold (BVS) System	Class D	An absorbable stent which is placed into a blood vessel (coronary artery) during angioplasty to help keep the coronary artery open.
11.	Cardiac Stents	Bifurcation Stent	Class C	Intended for improving the side branch luminal diameter of arterial bifurcation liaisons.
12.	Catheters	Fiberoptic Oximeter Catheter	Class B	Intended for monitoring the balance between oxygen delivery and consumption at the bedside
13.	Catheters	A-V Shunt or Fistula Adapter	Class B	A blood access device and accessories is a device intended to provide access to a patient's blood for haemodialysis or other chronic uses.
15.	Catheters	Transcervical(Aminoscope) Endoscope and	Class B	It is a device designed to permit direct viewing of the foetus and amniotic sac by means of an open tube introduced

		accessories		into the uterus through the cervix.
16.	Catheters	Forceps, endoscopic	Class B	Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.
17.	Catheters	Transabdominal (Fetoscope) Aminoscope and Accessories	Class C	It is a device designed to permit direct visual examination of the foetus by a telescopic system via abdominal entry. The device is used to ascertain foetal abnormalities
18.	Catheters	Anaesthetic Conduction Kit	Class C	An anaesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anaesthesia. The device may contain syringes, needles, and drugs.
19.	Catheters	Angiographic Guide Wire	Class D	It delivers radio opaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.
20.	Catheters	Cardiac Catherization Kit	Class D	Cardiac catheterization is a general term for a group of procedures that are performed using this method, such as coronary angiography and left ventricle angiography
21.	Catheters	Vena Cava Filter Sets	Class C	It is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava to treat various disease conditions.
22.	Catheters	Vessel Dialator for percutaneous Catheterization	Class B	A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
23.	Catheters	Tracheobronchial Suction Catheter	Class B	Clearing the airways of mucus, pus, or aspirated materials to improve oxygena tion and ventilation.
24.	Catheters	Cervical Drain	Class B	The device is used to avoid postoperative wound and respiratory complications such as excessive edema, hematoma, infection, re-intubation, delayed extubation, or respiratory distress

25.	Catheters	Rectal Balloon	Class B	Reducing the intrafraction motion and improving the sparing of rectal wall by reducing the rectal volume in the high-dose region, resulting in significant reduction in rectal toxicity.
26.	Catheters	Balloon for Cerebrovascular Occlusion	Class D	Balloon used to treat Blockage or closing of Cerebrovascular vessels/carotid arteries
27.	Catheters	Intra-Aortic System Balloon and Control	Class D	It is a mechanical device that increases myocardial oxygen perfusion while at the same time increasing cardiac output
28.	Catheters	Biliary Stone Retrieval Basket	Class B	Intend to extract stones in an antegrade fashion through an ampullary orifice previously treated by endoscopic sphincterotomy or less commonly with balloon dilation
29.	Catheters	Tracheostomy Tube/Tracheal Tube	Class B	A breathing tube inserted into a tracheotomyused to obtain a closed circuit for ventilation
30.	Catheters	Vial Adapter	Class B	It is indicated to allow multiple needleless access to injection medication vials for transfer or withdrawal of fluids from the vial.
31.	Catheters	Suprapubic, non-disposable Cannula	Class B	an emergency measure for the relief of acute urinary retention or condition which require temporary and permanent drainage of bladder.
32.	Catheters	Nasopharyngeal Catheter/Nasopharyngeal	Class A	A catheter (for adults) passed through the nares and advanced to the depth of the nasopharynx to remove air choke or obstruction. AResuscitator.
33.	Catheters	Esophageal obturator	Class B	Inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea.
34.	Catheters	Balloon Catheter for Retinal Reattachment	Class B	An instrument for reattachment of a detached retina to the inner wall of the eyeball. It can be inserted into the interior of the eyeball.
35.	Catheters	Gastric, Colonic, etc.) Irrigation and Aspiration Catheter	Class B	Used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract.

36.	Catheters	Suction Tip and Catheter	Class B	Suction Catheters feature a whistle tip and a thumb control port for precise and accurate suctioning.
37.	Catheters	Angiographic Catheter	Class B	Designed to provide a pathway for delivering contrast media to selected sites in the device vascular system including the carotid arteries.
38.	Catheters	Arterial Catheter	Class B	Intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature.
39.	Catheters	Balloon Type Catheter	Class B	"Soft" catheter with an inflatable "balloon" at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body.
40.	Catheters	Balloon Dialation Vessel Catheter	Class B	Intended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, femoral and peroneal arteries. These catheters are not for use in coronary arteries.
41.	Catheters	Bartholin Gland Catheter	Class B	Catheter is used for the treatmenti of abscesses and cysts of the Hartholin gland.
42.	Catheters	Bronchography Catheter	Class B	Intended to deliver therapeutic and diagnostic agents that are indicated or labeled for airway, tracheal or
43.	Catheters	Cholangiography Catheter	Class B	Diagnostic evaluation of the bile ducts during laparoscopic cholecystectomy procedures
44.	Catheters	Anesthetic Conduction Catheter	Class B	An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia
45.	Catheters	Anesthesia conduction filter	Class C	A microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid
46.	Catheters	Continuous Flush Catheter	Class B	Intended for the controlled and selective infusion of
47.	Catheters	Continous Irrigation Catheter	Class B	Intended to be used to introduce fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions.

48.	Catheters	Coude Catheters	Class B	It is a urinary catheter, It may be used to inject liquids used for treatment or diagnosis of bladder conditions.
49.	Catheters	Depezzer Catheter	Class B	A tubular, flexible instrument, passed t hrough body channels for withdrawal o f fluids from a body cavity.
50.	Catheters	Double lumen Female Urethrographic Catheter	Class B	Intended for vascular access infusion and withdrawal of blood, blood products, and fluids, plasma pheresis, hyperalimentation, central venous blood sampling and continuous and intermittent drag infusion.
51.	Catheters	Epidural Catheter	Class B	Epidural catheter is a very thin, flexible tube that is implanted into spine
52.	Catheters	Esophageal Balloon Catheter	Class B	intended for use in adult and adolescent populations
53.	Catheters	Eustachian Catheter	Class B	It is used to test Eustachian tube patency
54.	Catheters	Guiding Catheter	Class B	The guide catheter provides support for device advancement .
55.	Catheters	Haemodialysis Catheter	Class B	A catheter used for exchanging blood to and from the haemodialysis machine from the patient.
56.	Catheters	Central Venous Catheters	Class C	It is indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media.
57.	Catheters	Intramuscular Pressure Monitoring Catheter	Class B	A modified fibre optic transducer-tipped catheter system for measuring intramuscular pressures during exercise was determined.
58.	Catheters	Introducer Sheath	Class C	Intended to provide easier access to the femoral, popliteal and infrapopliteal arteries.
59.	Catheters	Intravenous Catheter	Class B	A catheter that is inserted into a vein fo r supplying medications or nutrients dir ectly into the bloodstream or for diagno sticpurposes such as studying blood pre ssure
60.	Catheters	Jejunostomy Catheter	Class B	Used for intraoperative feeding jejunostomy
61.	Catheters	Multiple Lumen Catheter	Class B	Intended for monitoring central venous pressure (CVP), sampling blood, and

				simultaneous administration of

				multiple IV solutions or drugs.
62.	Catheters	Nasal Oxygen Catheter	Class B	It is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help.
63.	Catheters	Embolic Filter system	Class D	It is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5mm.
64.	Catheters	Carotid Filter System	Class C	Used while performing angioplasty and stenting procedures in carotid arteries.
65.	Catheters	RETRIEVAL SNARE	Class C	intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy.
66	Catheters	RETRIEVAL SNARE	Class D	intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral system and the extra cranial neurovascular anatomy.
67.	Catheters	Nephrostomy Catheter	Class B	A nephrostomy is a tube that's used to drain urine from a kidney into a bag outside the body.
68.	Catheters	Peritoneal Dialysis Catheter	Class B	That allows dialysis fluid to enter the abdominal cavity, dwell inside for a while, and then drain back out again
69.	Catheters	Radiographic (Non Vascular) Catheter	Class B	Interventional radiologists obtain images using needles and narrow tubes called catheters, rather than by making large incisions into the body as in traditional surgery.
70.	Catheters	Rectal Catheter	Class B	It is inserted into the rectum in order to relieve flatulence which has been chronic and which has not been alleviated by other methods.
71.	Catheters	Retention Type Catheter	Class B	This type of catheter is placed into the bladder and secured there for a period of time.
72.	Catheters	Retention Type	Class B	It has a balloon at the distal end, which is inflated with sterile water or saline to

		Balloon Catheter		prevent the catheter from slipping out of the bladder
73.	Catheters	Salpngography Catheter	Class B	Used for injection of contrast medium into the fallopian tube(s) for selective

				salpingography.
74.	Catheters	Single Needle Hemodialysis Catheter/Blood lines	Class B	The single-needle dialysis, in which case only one cannula or a single-lumen catheter is used to access the blood
75.	Catheters	Straight Catheter	Class B	It is used in patients with neurogenic bladder or spinal cord injury, lessens the risk of urinary tract infection
76.	Catheters	Subclavian Catheter	Class B	Catheters can be placed in veins in the neck (internal jugular vein), chest (subclavian vein or auxiliary vein),
77.	Catheters	Suprapubic Catheter	Class B	A suprapubic catheter is a thin, sterile tube used to drain urine from bladder.
78.	Catheters	Umblical Artery Catheter	Class B	Umbilical artery catheterization provides direct access to the arterial blood supply and allows accurate measurement of arterial blood pressure, a source of arterial blood sampling, and intravascular access for fluids and medications
79.	Catheters	Upper Urinary Tract Catheter	Class B	The catheter to the bladder and subsequently to the upper urinary tract
80.	Catheters	Urethral Catheter/Nelaton Catheter/ Foley Catheter	Class B	A long, small gauge catheter designed f or insertion directly into a ureter, either through the urethra andbladder or post eriorly via the kidney.
81.	Catheters	Urethrographic Male Catheter	Class B	A catheter used to pass into a man's bladder.
82.	Catheters	Chorionic Villus Sampling Catheter	Class B	An ultrasound guides a thin catheter through the cervix to your placenta. The chorionic villi cells are gently suctioned into the catheter.
83.	Catheters	Sclerotherapy Needle/ Catheter	Class B	Sclerotherapy Needles are designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopic mucosal resection (EMR)
84.	Catheters	Water Jet Renal Catheter	Class B	A device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit.

85.	Catheters	Hemodialysis Catheter (Long Term)	Class C	A dialysis catheter is a catheter used for exchanging blood to and from the hemodialysis machine from the patient. The dialysis catheter contains two lumens: Venous. Arterial
86.	Catheters	Percuataneous Intravascular Long Term Catheter	Class C	The device allows for repeated access to the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood;
87.	Catheters	Percutaneous Long Term Intraspinal Catheter	Class C	To conduct a preimplantintra spinal infusion screening trial procedure prior to implanting a pump
88.	Catheters	Implanted Subcutaneous Intravascular Port & Catheter	Class C	The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood
89.	Catheters	Subcutaneous Intraspinal Port & Catheter	Class C	Catheters used for both epidural Intrathecal infusion include short-term externalized catheters and long-term catheters that are tunnelled in the subcutaneous tissue
90.	Catheters	Peripheral, Transluminal Angioplasty Catheter	Class C	A catheter for treating peripheral vascular diseases
91.	Catheters	Cardiac Thermodilution Catheter	Class D	A catheter used in thermodilution for in troduction of the cold liquid indicator i nto thecardiovascular system or for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions.
92.	Catheters	Cardiovascular Catheter	Class D	A thin, hollow tube called a catheter is inserted into a large blood vessel that leads to heart.
93.	Catheters	Cerebrospinal Catheter	Class D	For treatment or prevention of cranial/spinal cerebrospinal fluid fistula.
94.	Catheters	Atherectomy Coronary Catheter	Class D	A catheter containing a rotating cutter and a collecting chamber for debris, used for atherectomy and

				endarterectomy.
95.	Catheters	Electrode Recording Probe, Electrode Recording Catheter	Class D	A cardiac catheter containing one or more electrodes; it may be used to pace the heart or to deliver high energy shocks.
96.	Catheters	Oximetry catheters, Oximetry Paceport catheter	Class B	It is indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous oxygen saturation monitoring, and for infusing solutions
97.	Catheters	Embolectomy Catheter	Class D	indicated for the removal of fresh, soft emboli and
98.	Catheters	Flow Directed Catheter	Class B	Used for venous sampling and pressure monitoring.
99.	Catheters	Ultrasonic maging Catheter	Class B	intended for ultrasound examination of peripheral pathology only
100.	Catheters	Intraaortic Balloon Catheter	Class D	It is indicated for use in patients undergoing cardiopulmonary bypass.
101.	Catheters	Intracardiac Mapping, High Density Array Catheter	Class D	A high density array catheter once used in the right atrium to map and diagnosis complexarrhythmias and assess the effe ctiveness of ablation treatment.
102.	Catheters	Coronary Dilation Catheter	Class C	It is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
103.	Catheters	Intravascular Occluding Catheter	Class D	It is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms of intracranial blood vessels
104.	Catheters	Intravascular Diagnostic Catheter	Class D	Used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.
105.	Catheters	Occlusion Catheter	Class D	Insertion of a device or develop at any time during the course of intravenous (IV) therapy.

106.	Catheters	Percutaneous Catheter	Class D	A needle catheter getting access to a blood vessel, followed by the introduction of a wire through the lumen (pathway) of the needle.
107.	Catheters	Diagnostic Radiology Catheters	Class C	Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.
108.	Catheters	Perfusion Catheter	Class D	Perfusion catheter allowing localised perfusion of drugs not only into the vessel lumen, but also directly into the vessel wall at low pressure, during coronary intervention. -
109.	Catheters	Pericardium Drainage Catheter	Class D	Catheter drainage of the pericardium
110.	Catheters	Atherectomy Peripheral Catheter	Class D	Intended for use in atherectomy of the peripheral vasculature.
111.	Catheters	Septostomy Catheter	Class D	Used to enlarge interatrial openings
112.	Catheters	Thrombectomy Catheter	Class D	Thrombectomy catheter is specifically designed to treat deep vein thrombosis (DVT) in large-diameter upper and lower peripheral veins.
113.	Catheters	Transluminal, Coronary Angioplasty, Percutaneous Catheter	Class D	The catheter is placed in the opening or ostium of one the coronary arteries
114.	Catheters	Ventrricular Catheter	Class C	It is used to monitor pressure in patients with brain injuries, intracranial bleeds or other brain abnormalities that lead to increased fluid build-up.
115.	Catheters	Balloon Repair Kit Catheter	Class C	A device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to affect the repair or replacement.

116.	Catheters	Micro-catheter	Class C	It is intended to access the peripheral and neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and or diagnostic materials such as contrast media
117.	Catheters	Imaging Catheter	Class C	Intended for use with the various medical imaging consoles.
118.	Catheters	Central Nervous System Shunt including Neurological catheters and other Components	Class D	It is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume.
119.	Catheters	Endoscopic Ligation Devices	Class B	It is used for proximal and distal ligation of vessels during endoscopic vessel harvesting procedures.
120.	Catheters	Dialysate Tubing and Connector	Class B	A tubing connector adapted for peritoneal dialysis connections between tubing sets and containers of dialysate
121.	Catheters	Urinary Drainage Unit	Class B	A closed urinary drainage system consists of a catheter inserted into the urinary bladder and connected via tubing to a drainage bag
122.	Catheters	Tympanostomy Tube	Class C	It is a small tube inserted into the eardrum in order to keep the middle ear aerated for a prolonged period of time, and to prevent the accumulation of fluid in the middle ear
123.	Catheters	In-Vitro Fertilization/ Embryo Transfer Catheter	Class B	A cellular transfer catheter is provided for implantation of cellular material into the uterus of a patient

124.	Catheters	Sclerotherapy Needle/ Catheter	Class B	It is designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopic
125.	Catheters	Fluid Delivery tubing	Class B	Tube used to deliver fluid in body
126.	Catheters	Colon Tube	Class B	Colon Tubes also called "Tips" or even Catheters are inserted from the anus, through the rectum to deliver your enema solution into the colon (large intestine).
127.	Catheters	Connecting Tube	Class B	Used to provide connection to a drainage bag.
128.	Catheters	Decompression Tube	Class B	Decompression using a rectal tube may assist in the treatment only if the sigmoid colon is involved.
129.	Catheters	Double Lumen for intestinal Decompression and/or Intubation Tube	Class B	Tracheal intubation, usually simply referred to as intubation, is the placement of a flexible plastic tube into the trachea (windpipe) to maintain an open airway or to serve as a conduit through which to administer certain drugs.
130.	Catheters	Closed Wound Drainage Tube or System	Class B	A surgical drain is a tube used to remove pus, blood or other fluids from a wound. They are commonly placed by surgeons or interventional radiologists.
131.	Catheters	Oesophageal Blakemore Tube	Class B	It is a medical device inserted through the nose or mouth and used occasionally in the management of upper gastrointestinal hemorrhage due to oesophageal varices .
132.	Catheters	Oesophageal Sengtaken Tube	Class B	It is used only in emergencies where bleeding from presumed varices is impossible to control with medication alone
133.	Catheters	Feeding Tube	Class B	A feeding tube is a device that's inserted into your stomach through your abdomen. It's used to supply nutrition when you have trouble eating

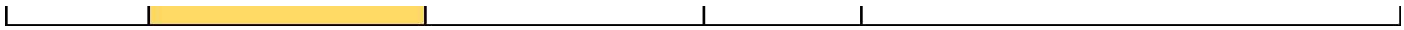
134.	Catheters	Gastro-Enterostomy Tube	Class B	Tube is placed through the abdominal wall into the stomach and then through the duodenum into the jejunum.
135.	Catheters	Gastrointestinal Tube	Class B	A gastrostomy tube (also called a G-tube) is a tube inserted through the abdomen that delivers nutrition directly to the stomach
136.	Catheters	Heart-Lung Bypass Unit Tube	Class B	A tube will be placed in your heart to drain blood to the machine.
137.	Catheters	Levine Tube	Class B	Used for the aspiration of gastric and intestinal contents and administration of tube feedings or medications.
138.	Catheters	NasoGastric Tube/ Ryles Tube	Class B	It is a special tube that carries food and medicine to the stomach through the nose. It can be used for all feedings or for giving a person extra calories.
139.	Catheters	Nephrostomy Tube	Class B	The nephrostomy tube drains urine from kidney into a collecting bag outside the body.
140.	Catheters	Orthodontic Tube	Class B	An orthodontic small metal part welded on the outside of a molar bank, which contains slots to holdarchwires, lip bu mpers, facebows and other devices use d to move the teeth.
141.	Catheters	Rectal Tube	Class B	A rectal tube, also called a rectal catheter, is a long slender tube which is inserted into the rectum in order to relieve flatulence .
142.	Catheters	Stomach Evaculator(Gastric Lavage) Tube	Class B	Passage of a tube via the mouth or nose down into the stomach followed by sequential administration and removal of small volumes of liquid.
143.	Catheters	Tonsil Suction Tube	Class B	Used to suck out stones in tonsils.
144.	Catheters	Tracheal (Endotracheal) Tube	Class B	Inserts the tube with the help of a laryngoscope, an instrument that permits to see the upper portion of the trachea, just below the vocal cords.
145.	Catheters	Closed Suction System	Class B	It is intended for endotracheal suctioning to provide a patient airway by removing excess fluids, secretions, exudates and transudate through the artificial airway.

146.	Catheters	Anastomosis Bypass Tube	Class C	It is anchored to mucosa and submucosa 3 centimetres proximal to a site of colocolonic anastomosis and later spontaneously evacuated by way of the rectum.
147.	Catheters	Endolymphatic Shunt Tube	Class B	During a surgical procedure in which it is placed in the membranous labyrinth of the inner ear to drain excess fluid.
148.	Catheters	Orthodontic Guide Wire	Class B	A wire conforming to the alveolar or dental arch that can be used with dental braces as a source of force in correcting irregularities in the position of the teeth
149.	Catheters	Intra-aortic balloon and control system	Class D	It is a medical device which is placed in the aorta to improve cardiovascular functioningduringcertain life-threatening emergencies.
150.	Catheters	Ventricular bypass (assistive)	Class D	A ventricular bypass (assistive) device is a device that assists the left or right ventricle in maintaining circulatory blood flow.
151.	Catheters	Catheter Guide Wire	Class D	It is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The PTCA Guide Wires are not to be used in the cerebral blood vessel
152	Catheters	Catheter Guide	Class D	It is intended to facilitate the placement of balloon ilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). PTCA Guide Wires are not to be used in the cerebral blood vessel.
153.	Catheters	Wire	Class C	An esophageal stent is a stent (tube) placed in the oesophagus to keep a blocked area open so the patient can swallow soft food and liquids
	Catheters			Biliary stents provide bile drainage from the gallbladder, pancreas and bile ducts to

154.		Biliary stents	Class C	the duodenum in conditions such as ascending cholangitis due to obstructing gallstones

155.	Catheters	Duodenal stents	Class C	Duodenal Stent is indicated for the palliative treatment of gastroduodenal obstructions
156.	Catheters	Colonic stent	Class C	A colonic stent is a flexible, hollow tube designed to keep a segment of the colon (large bowel) open when it has become blocked(obstructed). This blockage is commonly caused by a tumour inside the bowel or by outside pressure on the bowel wall.
157.	Catheters	Pancreatic stent	Class C	Pancreatic duct stents are often placed in patients who have chronic pancreatitis
158.	Catheters	Carotid Stent System	Class D	Indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization.
159.	Catheters	Peripheral Stent System	Class C	A Peripheral stent is a tube-shaped device placed in the peripheralarteries that supply blood into body organ.
160.	Contraceptives	Tubal Rings/ Fallopian Rings	Class C	Contraception devices for female sterilization
161.	Contraceptives	Male / Female Condoms	Class C	Condom with nonoxynol-9, micro-condom, prophylactic (condom) – latex sheath, non-latex, condoms with natural membrane, intra vaginal condoms etc.
162.	Contraceptives	Cu-T	Class D	Indicated for intrauterine contraception for up to 10 years.
163.	Disinfectants	Disinfectants	Class B	An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. It is intended to disinfect a medical device.
164.	Disposable Hypodermic Needles	Aspiration Needle	Class B	Used for either laparoscopic aspiration or injection

165.	Disposable Hypodermic Needles	Aspiration and Injection Needle	Class B	A thin needle is inserted into an area of abnormal-appearing tissue or body fluid. As with other types of biopsies, the sample collected during fine needle aspiration can help make a diagnosis or rule out conditions such as cancer.
166.	Disposable Hypodermic Needles	Insulin Needles/Pen Needles for insulin	Class B	Used to inject insulin for the treatment of diabetes.
167.	Disposable Hypodermic Needles	Medication Injector	Class B	A subcutaneous injection is a method of administering medication.
168.	Disposable Hypodermic Needles	Biopsy Needle Kit	Class B	A set of neurosurgical instruments designed to allow multiple biopsies from one or more targets in one trajectory
169.	Disposable Hypodermic Needles	Angiographic Needle	Class B	Angiographic needle has a unique hub design with an ergonomic feel and a black triangle indicator to orient the bevel.
170.	Disposable Hypodermic Needles	Mammary Biopsy Needle	Class B	The growth sample is suctioned out through a needle or cut out using a surgical procedure
171.	Disposable Hypodermic Needles	Blood Collecting Needle	Class B	Intended to be used with evacuated blood collection tube for collection of venous blood.
172.	Disposable Hypodermic Needles	Bone Marrow Needle	Class B	Needle inserted in Bone Marrow to collect sample
173.	Disposable Hypodermic Needles	Gynaecological Cerclage Needle	Class B	It is a loop like instrument used to suture the cervix.
174.	Disposable Hypodermic Needles	Cholangiography Needle	Class B	The aspirating needle is passed through the patient's skin and liver tissue until the tippenetrates one of the hepatic ducts
175.	Disposable Hypodermic Needles	Anaesthetic Conduction Needle	Class B	An anaesthesia conduction needle is a device used to inject local anaesthetics into a patient to provide regional anaesthesia
176.	Disposable Hypodermic Needles	Emergency Airway Needle	Class B	Emergency airway puncture is the placement of a hollow needle through the throat into the airway. It is done to treat life-threatening choking.



177.	Disposable Hypodermic Needles	Endoscopic Needle	Class B	Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope.
178.	Disposable Hypodermic Needles	Fistula Needle	Class B	To connect blood lines with the blood vessels through needles when dialysis is carried out
179.	Disposable Hypodermic Needles	Epidural Needle	Class B	Intended for transient delivery of anasthetics to provide regional anesthesia or to facilitate placement of an epidural catheter
180.	Disposable Hypodermic Needles	Gastro-Urology Needle	Class B	Intended for gastroenterology biopsy
181.	Disposable Hypodermic Needles	Single Lumen Hypodermic Needle	Class B	A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
182.	Disposable Hypodermic Needles	Neurosurgical Suture Needle	Class B	A needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.
183.	Disposable Hypodermic Needles	Oocyte Aspiration Needle	Class B	Mission to collect the maximum amount of undamaged oocytes in a short time as possible.
184.	Disposable Hypodermic Needles	Pneumoperitoneum Simple Needle	Class B	Inserting a Veress needle through the abdominal wall inside the peritoneal cavity.
185.	Disposable Hypodermic Needles	Prefillable Glass Barrel with needle	Class B	Intended for the automatic self-administration of drugs and biologics from standard Glass Barrel.
186.	Disposable Hypodermic Syringes	Injector Type actuator syringe	Class C	A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.
187.	Disposable Hypodermic Syringes	Aspiration Syringe	Class B	Used for either laparoscopic aspiration or injection
188.	Disposable Hypodermic Syringes	Irrigating Syringes	Class B	cleaning debris away from the area the dentist is working on

189.	Disposable Hypodermic Syringes	Insulin Syringes	Class B	Used to inject insulin for the treatment of diabetes.
	Disposable Hypodermic Syringes	Auto Disable Syringe for single use	Class B	Intend to inject fluids into or withdraw fluids from the body.
191.	Disposable Hypodermic Syringes	Traditional single use syringe without safety feature (Sterile hypodermic syringes for single use)	Class B	Intend to inject fluids into or withdraw fluids from the body.
192.	Disposable Hypodermic Syringes	Auto-disable (AD) syringes for immunization	Class B	Intend to inject fluids into or withdraw fluids from the body.
193.	Disposable Hypodermic Syringes	Re use Prevention (RUP) syringes for therapeutic injections (Syringes with re-use prevention feature)	Class B	Intend to inject fluids into or withdraw fluids from the body.
194.	Disposable Hypodermic Syringes	Sharps Injury Protection (SIP) - Plastic needle shield to be added to a syringe	Class B	Intend to inject fluids into or withdraw fluids from the body.
195.	Disposable Perfusion Sets	Sharps Injury Blood Administration kits	Class B Class B	It is used to administer blood from a container to a patient's vascular system through a needle or catheter inserted

				into a vein
196.	Disposable Perfusion Sets	Measured Volume IV Set	Class B	It is intended for use in the administration of fluids from a container into the patient's vascular system through a vascular access device.
197.	Disposable Perfusion Sets	Transfusion or Perfusion sets for single use	Class B	Transfusion Set is used to administer blood/drugs to a patient's vascular system through a needle or catheter inserted into a vein.
198.	Disposable Perfusion Sets	Custom Perfusion System	Class C	Indicated for use in the extra corporeal circuit during cardio pulmonary bypass surgery procedure.
199.	Disposable Perfusion Sets	Manifolds	Class B	Indicated for fluid flow directional control and for providing access port/ports for administration of a solution.
200.	Disposable Perfusion Sets	3 way stop cock as an accessory to perfusion sets	Class B	It is indicated for fluid flow directional control and for providing access port for administration of solution, withdrawal of fluid and pressure monitoring
201.	Disposable Perfusion Sets	Y-Connector as an accessory to perfusion sets	Class A	It can be used to connect to a perfusion sets or catheter for infusion of contrast media etc.
202.	Disposable Perfusion Sets	I V Flow regulator	Class B	An IV system and administration device offering precision care and consistent delivery.
203.	Disposable Perfusion Sets	Extension Sets	Class B	Extension sets are sterile devices for single use only. They are intended to be used as part of a system for the infusion of fluids/medications in medical applications.
204.	Disposable Perfusion Sets	Infusion Pump or Elastomeric Infusion Device	Class C	The Infusion Pumps intended for slow, continuous delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), and subcutaneous or epidural infusion of medications directly into an intra-operative site or subcutaneously for post operative pain management.

205.	Drug Eluting Stents	Drug eluting stent	Class D	Stent, coronary, drug-eluting - a metal scaffold with a drug coating placed via a delivery catheter into the coronary artery or saphenous vein graft to maintain the lumen. The drug coating is intended to inhibit restenosis.
206.	Heart Valves	Heart valve	Class D	A device intended to perform the function of any of the heart's natural valves.
207.	Internal Prosthetic Replacements	Tissue Expanders	Class C	Intended to be used in breast reconstruction or treatment of soft tissue deformities such as used following mastectomy or for treatment of underdeveloped breasts.
208.	Internal Prosthetic Replacements	Bio Patches	Class C	Intended for reconstruction and repair of defects of pericardium.
209.	Internal Prosthetic Replacements	Vascular graft/occluders/Cardiac Patches	Class D	Intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access.
210.	Internal Prosthetic Replacements	Vascular embolization device	Class D	It is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors.
211.	Internal Prosthetic Replacements	Voice / laryngeal Prothesis	Class C	The device is intended to direct pulmonary air flow to the pharynx in the absence of the larynx, for permitting esophageal speech.
212.	Internal Prosthetic Replacements	Cardiovascular prosthetic devices	Class D	An intra-cardiac patch or pledgete which is a medical device placed in the heart and is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

213.	Internal Prosthetic Replacements	Hearing Prosthesis System	Class C	The prostheses are intended for partial ossicular replacement to restore functionality to the middle ear .
214.	Internal Prosthetic Replacements	Annuloplasty ring	Class C	An annuloplasty ring implanted around the mitral or tricuspid heart valve for reconstructive treatment.
215.	Internal Prosthetic Replacements	Total ossicular replacement prosthesis	Class D	It is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.
216.	Internal Prosthetic Replacements	Ear, nose, and throat and facial synthetic polymer material or implant	Class C	It is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck.
217.	Internal Prosthetic Replacements	Mandibular implant facial prosthesis	Class C	Intended to be implanted for use in the functional reconstruction of mandibular deficits.
218.	Internal Prosthetic Replacements	Sacculotomy tack (Cody tack)	Class C	Intended to be implanted to relieve the symptoms of vertigo.
219.	Internal Prosthetic Replacements	Endolymphatic shunt	Class C	Intended to be implanted to relieve the symptoms of vertigo.
220.	Internal Prosthetic Replacements	An endolymphatic shunt tube with valve	Class C	It is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss.
221.	Internal Prosthetic Replacements	Fallopian tube prosthesis	Class C	A device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.
222.	Internal Prosthetic Replacements	Vaginal stent	Class C	A device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.
223.	Internal Prosthetic Replacements	Eye sphere implant	Class D	An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera left intact.

224.	Internal Prosthetic Replacements	Keratoprosthesis	Class D	It is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye.
225.	Internal Prosthetic Replacements	Bone heterograft	Class D	Intended to be implanted that is made from bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.
226.	Internal Prosthetic Replacements	Intramedullary fixation rod	Class C	Intended to be implanted into the medullary (bone marrow) canal of long bones for the fixation of fractures.
227.	Internal Prosthetic Replacements	Endosseous dental implant	Class C	Intended to be surgically placed in the bone of jaw arches to provide support for prosthetic devices, such as artificial teeth.
228.	Internal Prosthetic Replacements	Dental implant	Class C	A dental implant is a surgical component that interfaces with the bone of the jaw or skull to support a dental prosthesis such as crown, bridge, denture, facial prosthesis or to act as an orthodontic anchor.
229.	Internal Prosthetic Replacements	Bone grafting material	Class C	Intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.
230.	Internal Prosthetic Replacements	Total temporomandibular joint prosthesis	Class D	Intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.
231.	Internal Prosthetic Replacements	Glenoid fossa prosthesis	Class D	Intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.
232.	Internal Prosthetic Replacements	Mandibular condyle prosthesis	Class D	Intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.
233.	Internal Prosthetic Replacements	An interarticular disc prosthesis	Class D	Intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

234.	Internal Prosthetic Replacements	Penile inflatable implant	Class D	A penile inflatable implant is a device which is implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. This device is used in the treatment of erectile impotence.
235.	Internal Prosthetic Replacements	Penile rigidity implant	Class C	A device that is implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction
236.	Internal Prosthetic Replacements	Artificial Urinary Sphincters implants	Class C	It is used to prevent incontinence by occluding the urethra.
237.	Internal Prosthetic Replacements	Implanted mechanical/hydraulic urinary continence device	Class C	An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra.
238.	Internal Prosthetic Replacements	Cochlear implant	Class D	A cochlear implant is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.
239.	Internal Prosthetic Replacements	Retinal implant	Class D	The retinal implant is meant to partially restore useful vision to people who have lost their vision due to degenerative eye conditions
240.	Internal Prosthetic Replacements	Breast implant	Class C	Breast implant is used to increase the breast size.
241.	Internal Prosthetic Replacements	Tracheal prosthesis	Class C	It is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree
242.	Internal Prosthetic Replacements	Polymeric Surgical Mesh	Class C	The polymeric mesh comprises an absorbable polymeric fibre and a non-absorbable polymeric fibre knitted together to form an interdependent, co-knit mesh structure.
243.	Internal Prosthetic Replacements	Endosseous dental implant abutment	Class C	Intended for use as an aid in prosthetic rehabilitation.

244.	Internal Prosthetic Replacements	A testicular prosthesis	Class D	A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.
	Internal Prosthetic Replacements	Aneurysm Implant (detachable coils/clips)	Class D	It is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
246.	Intra Ocular Lenses	Intraocular lens	Class C	Intraocular lens (IOL) are lens implanted in the eye used to treat cataracts or myopia
247.	IV Cannulae	Intravenous Cannula	Class B	The IV Cannula is a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices .
248.	IV Cannulae	Arterial Cannula	Class B	Inserted into an artery, commonly the radial artery, and is used during major operations and in critical care areas to measure beat-to-beat blood pressure and to draw repeated blood samples.
249.	IV Cannulae	Coronary Artery Cannula	Class B	Cannulation technique for left-sided coronary artery surgery.
250.	IV Cannulae	Hemodialysis Cannula	Class B	Allowing the arterial blood to flow to the dialyzer and the dialyzed blood to return from the dialyzer to the circulation through the cannula in the vein.
251.	IV Cannulae	Vena Cava Cannula	Class B	Inserted into Vena Cava, taking deoxygenated blood to heart.
252.	IV Cannulae	Venous Cannula	Class B	It is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.
253.	IV Cannulae	Ventricular Cannula	Class B	For use in neurosurgical procedures. It is specially designed to penetrate delicate brain tissue and give continued access to brain's ventricular system.
254.	IV Cannulae	A-V Shunt Cannula	Class C	It is inserted into one of the client's blood vessels to facilitator repeated hemodialysis.

255.	IV Cannulae	Cannulact or Lymph Duct	Class B	A lymph duct is a great lymphatic vessel that empties lymph into one of the subclavian veins
256.	Orthopaedic Implants	Intra Osseous Fixation Wire	Class C	Stabilization of fractured bony parts by direct fixation to one another with surgical wires
257.	Orthopaedic Implants	Cortical Fixation Implant / rigidloop Adjustable Cortical Fixation System	Class C	Cortical Fixation System is a machined titanium implant designed to provide fixation in the repair of tendons and ligaments.
258.	Orthopaedic Implants	Intervertebral Body Fusion Device / Fuse Spinal System	Class C	It is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels.
259.	Orthopaedic Implants	Bone Wire	Class C	Intended to be used for bone stabilization in the hand and wrist.
260.	Orthopaedic Implants	Bone cap	Class C	Intended to be implanted to cover the end of a bone.
261.	Orthopaedic Implants	Orthopedic implant & accessories	Class C	Intended to replace a missing joint or bone or to support a damaged bone.
262.	Orthopaedic Implants	Intervertebral body fusion device	Class D	The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion
263.	Orthopaedic Implants	Pedicle screw spinal system	Class C	It is used to intended to provide immobilization and stabilization of spinal segments
264.	Orthopaedic Implants	Ankle joint metal/composite semi-constrained cemented prosthesis	Class C	An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint.
265.	Orthopaedic Implants	Ankle joint metal/polymer non-constrained cemented prosthesis	Class C	A device intended to be implanted to replace an ankle joint. The device limits minimally translation in one or more planes. It has no linkage across-the-joint.
266.	Orthopaedic Implants	Elbow joint metal/polymer constrained cemented prosthesis	Class C	An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint.

267.	Orthopaedic Implants	Elbow joint metal/polymer semi-constrained cemented prosthesis	Class C	An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint
268.	Orthopaedic Implants	elbow joint radial (hemi-elbow) polymer	Class C	An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.
269.	Orthopaedic Implants	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Class C	A device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulumhumeri
270.	Orthopaedic Implants	elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Class C	A device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulumhumeri
271.	Orthopaedic Implants	Finger joint metal/metal constrained uncemented prosthesis	Class C	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint
272.	Orthopaedic Implants	Finger joint metal/metal constrained cemented prosthesis	Class C	A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint
273.	Orthopaedic Implants	Finger joint polymer constrained prosthesis	Class C	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint
274.	Orthopaedic Implants	hip joint metal constrained cemented or uncemented prosthesis	Class D	A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint
275.	Orthopaedic Implants	Hip joint metal/polymer constrained cemented or uncemented	Class D	A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint

		prosthesis		
276.	Orthopaedic Implants	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	Class D	It is a prosthesis intended to be implanted to replace a hip joint
277.	Orthopaedic Implants	hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	Class D	Intended to be implanted to replace a hip joint
278.	Orthopaedic Implants	hip joint metal/composite semi-constrained cemented prosthesis	Class C	A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint
279.	Orthopaedic Implants	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis	Class C	Intended to be implanted to replace a hip joint
280.	Orthopaedic Implants	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.	Class C	Intended to be implanted to replace a hip joint
281.	Orthopaedic Implants	A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a	Class C	Intended to be implanted to replace part of a knee joint

		knee joint		
282.	Orthopaedic Implants	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
283.	Orthopaedic Implants	Wrist joint carpal lunate polymer prosthesis	Class C	Intended to be implanted to replace the carpal lunate bone of the wrist.
284.	Orthopaedic Implants	Wrist joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint.
285.	Orthopaedic Implants	Wrist joint metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint
286.	Orthopaedic Implants	Wrist joint polymer constrained prosthesis	Class C	Intended to be implanted to replace a wrist joint
287.	Orthopaedic Implants	Wrist joint carpal trapezium polymer prosthesis	Class C	Intended to be implanted to replace the carpal trapezium bone of the wrist
288.	Orthopaedic Implants	Wrist joint carpal scaphoid polymer prosthesis	Class C	Intended to be implanted to replace the carpal scaphoid bone of the wrist.
290.	Orthopaedic Implants	Toe joint phalangeal (hemi-toe) polymer prosthesis	Class C	Intended to be implanted to replace the base of the proximal phalanx of the toe.
291.	Orthopaedic Implants	Toe joint polymer constrained prosthesis	Class C	Intended to be implanted to replace the first metatarsophalangeal (big toe) joint

292.	Orthopaedic Implants	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.	Class C	A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
293.	Orthopaedic Implants	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	Class C	It is intended to be implanted to replace part of a shoulder joint
294.	Orthopaedic Implants	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis	Class C	It is a device intended to be implanted to replace a shoulder joint
295.	Orthopaedic Implants	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
296.	Orthopaedic Implants	shoulder joint metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint
297.	Orthopaedic Implants	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
298.	Orthopaedic Implants	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint
299	Orthopaedic Implants	knee joint femoral (hemi-knee) metallic uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.

300.	Orthopaedic Implants	knee joint patellofemorotibial metal/polymer	Class C	Intended to be implanted to replace a knee joint
301.	Orthopaedic Implants	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.	Class C	Intended to be implanted to replace a knee joint
302.	Orthopaedic Implants	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a knee join
303.	Orthopaedic Implants	knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	Class C	It is intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia
304.	Orthopaedic Implants	Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
305.	Orthopaedic Implants	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
306.	Orthopaedic Implants	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
307.	Orthopaedic Implants	Knee joint femorotibial metal/polymer constrained cemented	Class C	Knee joint femorotibial metal/polymer constrained cemented prosthesis

		prosthesis		
308.	Orthopaedic Implants	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
309.	Orthopaedic Implants	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
310.	Orthopaedic Implants	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint
311.	Orthopaedic Implants	Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.	Class C	Intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck
312.	Orthopaedic Implants	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	Class D	Intended to be implanted to replace a hip joint
313.	Orthopaedic Implants	hip joint metal constrained cemented or uncemented prosthesis	Class D	Intended to be implanted to replace a hip joint
314.	Orthopaedic Implants	Hip joint metal/polymer constrained cemented or uncemented	Class D	Intended to be implanted to replace a hip joint

		prosthesis		
315.	Orthopaedic Implants	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint
316.	Orthopaedic Implants	A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	Class D	Intended to be implanted to replace the head and neck of the femur
317.	Orthopaedic Implants	A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	Class D	Intended to be implanted to replace the head and neck of the femur
318.	Orthopaedic Implants	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.	Class D	Intended to be implanted to replace the head and neck of the femur
319.	Orthopaedic Implants	A hip joint (hemi-hip) acetabular metal cemented prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint
320.	Orthopaedic Implants	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.	Class D	Intended to be implanted to replace a portion of the hip joint
321.	Orthopaedic Implants	Plates, clipersScrews	Class C	rigid, limb brace, lumbar, lumbo-sacral, rib fracture, sacroiliac, thoracic oethosis.
322.	Orthopaedic Implants	Spinal intervertebral body fixation orthosis	Class C	The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.

323.	Orthopaedic Implants	Spinal interlaminal fixation orthosis	Class C	A device intended to be implanted made of an alloy, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is used primarily in the treatment of scoliosis
324.	Orthopaedic Implants	Resorbable calcium salt bone void filler device	Class C	A resorbable calcium saltbone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis
325.	Orthopaedic Implants	Smooth or threaded metallic bone fixation fastener	Class C	It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.
326.	Orthopaedic Implants	Sacroiliac joint fixation	Class C	The sacroiliac joints fixation may serve as protective mechanism for the lumbosacral region.
327.	Orthopaedic Implants	Cervical Artificial Disc	Class D	Cervical Artificial Disc is indicated for reconstruction of the disc.
328.	Scalp Vein Set	Scalp Vein Set	Class B	Intended to be used for insertion into the patient's vascular system (single use only) as an in-dwelling device to administer fluids intravenously or to sample blood.
329.	Surgical Dressings	Surgical Staples	Class B	Surgical staples are specialized staples used in surgery in place of sutures to close skin wounds, connect or remove parts of body during surgery.
330.	Surgical Dressings	Surgical Dressings	Class A	Dressing aerosol, non-adherent, dressing, periodontal, kit, dressing pad, dressing.
331.	Surgical Dressings	Surgical Dressings	Class B	Dressing-gel, dressing- permeable, moisture dressing, tracheostomy tube dressing, wound and burn dressings, hydrogel dressing, wound and burn, occlusive.
332.	Surgical Dressings	Cotton Grudges		Adhesive bandages, Gauge bandages, Medical Absorbent (fiber) bandages.

333.	Surgical Dressings	Wound Dressings/Bacteriostatic Wound Dressings	Class C	Includes Beads, Hydrophilics For Wound Exudate Absorption for wound care.
334.	Surgical Dressings	Casting tapes/Splint Rolls	Class B	A prosthetic and orthotic accessory, intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis.
335.	Surgical Dressings	Haemostatic Gelatine Sponge /Haemostat	Class C	Intended for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.
336.	Surgical Dressings	Surgical Dressings	Class C	Material dressing, surgical, polylactic acid dressings.
337.	Surgical Dressings	Absorable Hemostatic Based	Class D	An absorbable haemostatic agent or dressing is a device intended to produce haemostasis by accelerating the clotting process of blood. It is absorbable.
338.	Surgical Dressings	Umbilical occlusion device	Class A	These devices may be a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.
339.	Surgical Dressings	Bolster Suture	Class A	Non-latex plastic bolsters are used to hinder pressure of any temporary suture against the body during surgery.
340.	Surgical Dressings	Suture Non Absorable Synthetic	Class C	Non-absorbable suture is comprised of surgical steel as well as synthetic non-absorbable sutures for use in general soft tissue approximation and ligation.
341.	Surgical Dressings	Suture Absorable	Class C	The device is intended for use in general soft tissue approximation and ligation.
342.	Surgical Dressings	Endovascular suturing system	Class C	It is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery.
343.	Surgical Dressings	Fixation, non-absorbable for pelvic use	Class C	Attaching suture or stapling ligaments of the pelvic floor.
344.	Surgical Dressings	Tissue adhesive for the topical use	Class C	Intended for topical closure of surgical incisions including laparoscopic incisions and simple traumatic lacerations.

345.	Surgical Dressings	Tissue adhesive for non-topical use	Class D	Intended for use in adhesion of internal tissues and vessels, for example; adhesives used in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery.
346.	Surgical Dressings	Alcohol Swabs	Class A	It is a single use, sterile device containing 70% Isopropyl alcohol used for scrubbing and allowing drying and will disinfect needless access sites prior to use..
347.	Surgical Dressings	Ligature Wire	Class B	offer a spot-welded auxiliary hook which may be added to any bracket by simply tying in the arch wire
348.	Surgical Dressings	Surgical Sealant	Class B	For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
349.	Surgical Dressings	Wound Closure Device	Class B	Wound Closure Devices are indicated for soft tissue approximation.
350.	Surgical Dressings	Intracardiac patch	Class D	intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

(B) List of In Vitro Diagnostics Medical Devices under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

S. N.	Category	*in vitro* diagnostic medical device	Risk Class	Intended use
	Clinical Chemistry Reagents/ Kits for estimation of various Parameters exemplified as:			
1.		Acid Phosphatase (total or prostatic) test reagents/kits	Class B	An acid phosphatase (total or prostatic) test reagent/kit is a medical device, intended for the estimation of acid phosphatase in serum/plasma.
2.		Albumin test reagents/kits	Class B	An albumin test reagent/kit is a medical device intended for the estimation of albumin in serum/plasma.
3.		Alkaline phosphatase or isoenzymes test reagents/kits	Class B	An alkaline phosphatase or isoenzymes test reagent/kit is a medical device intended for the estimation of alkaline phosphatase or its isoenzymes in serum/plasma.
4.		Ammonia test reagents/kits	Class B	An ammonia test reagent/kit is a medical device intended for the estimation of ammonia levels in blood, serum/plasma.
5.		Amylase test reagents/kits	Class B	An amylase test reagent/kit is a medical device intended for the estimation of the enzyme amylase in serum, saliva / urine.
6.		Bicarbonate / carbon dioxide test reagents/kits	Class B	A bicarbonate/carbon dioxide test reagent/kit s a medical device for the estimation of bicarbonate/carbon dioxide in plasma, serum/whole blood.
7.		bilirubin (total and direct) test reagents/kits	Class B	A bilirubin (total and direct) test reagent/kit is a medical device intended for the estimation of bilirubin (total and direct) in serum/plasma.
8.		Calcium test reagents/kits	Class B	A calcium test reagent/kit is a medical device intended for the estimation of total calcium in serum.

9.		Chloride test reagents/kits	Class B	A chloride test reagent/kit is a medical device intended for the estimation of chloride in plasma, serum, sweat /urine.
10.		cholesterol (total) test reagents/kits	Class B	A cholesterol (total) test reagent/kit is a medical device intended for the estimation of cholesterol in serum or plasma.
11.		HDL cholesterol test reagents/kits	Class B	A HDL cholesterol test reagent/kit is a medical device intended for the estimation of HDL cholesterol in serum / plasma.
12.		LDL cholesterol test reagents/kits	Class B	A LDL cholesterol test reagent/kit is a medical device intended for the estimation of LDL cholesterol in serum/plasma.
13.		Lipoproteinstest reagents/kits	Class B	A lipoprotein test reagent/kit is a medical device intended for the estimation of lipoproteins in serum / plasma.
14.		Cholinesterase test reagents/kits	Class B	A cholinesterase test reagent/kit is a medical device intended for the estimation of cholinesteral in serum /plasma. .
15.		Creatine Kinase and its isoenzymestest reagents/kits	Class B	A creatine phosphokinase/creatine kinase or isoenzymes including CKMB, CKBB and CKMM test reagent/kit is a medical device intended for the estimation of the enzyme creatine phosphokinase or its isoenzymes in serum / plasma. .
16.		Copper test reagents/kits	Class B	Copper test reagent/kit is a medical device intended for the estimation of copper in plasma, serum / urine.
17.		Creatinine test reagents/kits	Class B	A creatinine test reagent/kit is a medical device intended for the estimation of creatinine in serum, plasma / urine.
18.		Gamma GlutamylTransferase (GGT) and isoenymes test reagents/kits	Class B	A Gamma Glutamyl Transferase (GGT) and isoenzymes test reagent/kit is a medical device intended for the estimation of the enzyme Gamma GlutamylTransferase (GGT) in serum / plasma.

19.		Glucose test reagents/kits	Class B	A Glucose test reagent/kit is a medical device intended for the estimation of glucose in blood/plasma/ body fluids.
20.		Glucose-6-Phosphate Dehydrogenase (G6PD) and its isoenzymes test reagents/kits	Class B	A Glucose-6-Phosphate Dehydrogenase(G6PD)test reagents/kit is a medical device intended for the estimation of Glucose-6-Phosphate Dehydrogenase or its isoenzymes in serum / plasma. .
21.		Glycosylated Hemoglobin or its variants test reagents/kits	Class B	Glycosylated Hemoglobin or its variants test reagents/kits are medical devices intended for the estimation of glycosylated hemoglobin or its variants including A1a, A1b, and A1c in blood.
22.		Hemoglobin test reagents/kits	Class B	A hemoglobin test reagent/kit is a medical device intended for the estimation of hemoglobin in blood.
23.		Iron test reagents/kits	Class B	An iron test reagent/kit is a medical device intended for the estimation of iron in serum /plasma.
24.		Ferritin test reagents/kits		An Ferritin test reagent/kit is a medical device intended for the estimation of ferritin in serum / plasma
25.		Iron-binding capacity test reagents/kits	Class B	Iron-binding capacity test reagents/kits are medical devices intended for the estimation of iron-binding capacity in serum / plasma.
26.		Lactate Dehydrogenase and its isoenzymes test reagents/kits	Class B	A Lactate Dehydrogenase and its isoenzymes test reagent/kit is a medical device intended for the estimation of enzyme Lactate Dehydrogenase and its isoenzymes in serum / plasma.
27.		Lipase test reagents/kits	Class B	A lipase test reagent/kit is a medical device intended for the estimation of lipase in serum / plasma.
28.		Magnesium test reagents/kits	Class B	A magnesium test reagent/kit is a medical device intended for the estimation of magnesium levels in serum / plasma.

29.		Phosphorus (inorganic) test reagents/kits	Class B	A phosphorus (inorganic) test reagent/kit is a medical device intended for the estimation of inorganic phosphorus in serum, plasma / urine.
30.		Potassium test reagents/kits	Class B	A potassium test reagent/kit is a medical device intended for the estimation of potassium in serum, plasma / urine.
31.		Aspartate Amino Transferase (AST/SGOT) test reagents/kits	Class B	An Aspartate Amino Transferase (AST/SGOT) test reagent/kit is a medical device intended for the estimation of the enzyme Aspartate Amino Transferase (AST/SGOT) in serum / plasma.
32.		Alanine Amino Transferase (ALT/SGPT) test reagents/kits	Class B	An Alanine Amino Transferase (ALT/SGPT) test reagent/kit is a medical device intended for the estimation of enzyme Alanine Amino Transferase (ALT/SGPT) in serum / plasma.
33.		Sodium test reagents/kits	Class B	A Sodium test reagent/kit is a medical device intended for the estimation of sodium in serum/ plasma / urine.
34.		Total protein test reagents/kits	Class B	A Total Protein test reagent/kit is a medical device intended for the estimation of total protein(s) in serum / plasma.
35.		Protein (fractionation) test reagents/kits	Class B	A Protein (fractionation) test reagent/kit is a medical device intended for the estimation of protein fractions in blood, urine, cerebrospinal fluid / other body fluids.
36.		Protein-bound iodine test reagents/kits	Class B	A Protein-bound iodine test reagent/kit is a medical device intended for the estimation of protein-bound iodine in serum / plasma.
37.		Triglycerides test reagents/kits	Class B	A Triglyceride test reagent/kit is a medical device intended for the estimation of triglycerides in serum / plasma.

38.		Urea (BUN) test reagents/kits	Class B	A Urea (BUN) test reagent/kit is a medical device intended for the estimation of urea/Blood Urea Nitrogen (BUN) in plasma/ serum / urine.
39.		Uric Acid test reagents/kits	Class B	A Uric Acid test reagent/kit is a medical device intended for the estimation of uric acid in serum/ plasma / urine.
40.		Micro-Protein test reagents/kits	Class B	A Micro-protein test reagent/kit is a medical device intended for the estimation of micro-proteins including micro-albumin in urine.
41.		Zinc test reagents/kits	Class B	A Zinc test reagent/kit is a medical device intended for the estimation of zinc in serum / plasma.
42.		Other clinical chemistry test reagents/kits	Class B*	Clinical chemistry test reagent/kit intended for the estimation of analytes/ parameters (other than listed above) in serum/ plasma/ urine or other body fluids.
	Hematology Reagents/ Kits for			
43.	**estimation of Complete Blood Counts ,**	Blood cell Diluents	Class B	A blood cell Diluent is a medical device used to dilute blood for further testing, such as Complete Blood Count(CBC) .
44.	**exemplified as:**	Lyse reagents/kits for differential counts	Class B	A Lyse reagent/kit is a medical device used for lysing of cells for the estimation of Complete Blood Count(CBC).
45.		Rinse/Detergent/Cleaners reagents/kits	Class B	A Rinse/Detergent/Cleaner reagent/kit is a medical device used for cleaning various parts of Hematology analyzers like probes, needles, baths, tubing etc.
	Reagents/ Kits for estimation of parameters in the urine, exemplified as:			
46.		Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific	Class B	Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific gravity/Urobilinogen Nitrite / pH /

		gravity/Urobilinogen Nitrite / pH / Protein / Albumin & other urinary analytes test reagents /Strips/kits		Protein / Albumin & other urinary analytes test reagents /Strips/kits, are medical devices intended for the preliminary estimation of diagnostic markers in urine.
	In - vitro			
47.	**Diagnostic Medical Devices for Self -Testing**	Glucose test reagents/kits	Class B	A glucose test reagent/kit is a medical device intended for the preliminary self testing of glucose levels in blood/body fluids.
48.		Human Chorionic Gonadotropin (hCG) test reagents/kits	Class B	A human Chorionic Gonadotropin (hCG) test reagent/kit is a medical device intended for the preliminary self testing of hCG in urine/body fluids.
49.		Luteinizing Hormone (LH) test reagents/kits	Class B	A Luteinizing Hormone (LH) test reagent/kit is a medical device intended for the preliminary self testing of Luteinizing Hormone (LH) in urine/body fluids.
50.		Glycosylated hemoglobinor its variants Test reagents/kits	Class B	Glycosylated Hemoglobin or its variants test reagents/kits are medical devices intended for the preliminary self testing of Glycosylated Hemoglobin or its variants including A1a, A1b, and A1c in blood.
51.		Cholesterol test reagents/kits	Class B	A Cholesterol test reagent/kit is a medical device intended for preliminary self testing of cholesterol in blood /body fluids.
52.		Follicle Stimulating Hormone (FSH) test reagents/kits	Class B	A Follicle Stimulating Hormone (FSH) test reagent/kit is a medical device intended for the preliminary self testing of Follicle Stimulating Hormone (FSH) in urine /body fluids
53.		Other In - vitro Diagnostic Medical Devices for Self - Testing	Class B*	

54.	**In - vitro Diagnostic Medical Device for near patient testing**			
55.		Blood Gas Analysis test reagents/kits	Class C	A Blood Gas Analysis test reagent/kit for near patient testing, is a medical device intended for the estimation of certain gases (such as oxygen and carbon dioxide etc.) dissolved in arterial blood.
56.		Anticoagulant monitoring test reagents/kits	Class C	An Anticoagulant monitoring test reagent/kit for near patient testing, is a medical device intended for the estimation of coagulation parameters (such as PT, TT, APTT etc.) in plasma/blood.
57.		Diabetes management test reagents/kits	Class C	A Diabetes management test reagent/kit for near patient testing, is a medical device intended for the of monitoring of diabetes in body fluids.
58.		C- Reactive Protein (CRP)test reagents/kits	Class C	A C- Reactive Protein (CRP) test reagent/kit for near patient testing, is a medical device intended for the estimation of C -Reactive Protein (CRP) in serum and other body fluids
59.		H. pylori test reagents/kits	Class C	An H. pylori test reagent/kit for near patient testing, is a medical device intended for the estimation of H. pylori in blood/body fluids.
60.		Troponin test reagents/kits	Class C	A Troponin test reagent/kit for near patient testing, is a medical device intended for the estimation of Troponin T,I and its variants in blood/body fluids
61.		Other in vitro Diagnostic Medical Devices for near patient test reagents/kits	Class **C***	In vitro Diagnostic Medical Device for near patient test reagent/kit intended for the estimation of analytes/ parameters (other than listed above) in serum, plasma, urine or other body fluids.
	Reagents/ Kits for estimation of			

62.	**parameters of ToRCH& other infectious agents exemplified as under:**	Toxoplasma gondii test reagents/kits	Class C	A Toxoplasma gondii test reagent/kit is a medical device intended for the detection of Toxoplasma gondii in serum/body fluids.
63.		Rubella virus l test reagents/kits	Class C	A Rubella virus test reagent/kit is a medical device intended for the detection of Rubella virus in serum/body fluids.
64.		Cytomegalovirus test reagents/kits	Class C	A Cytomegalovirus test reagent/kit is a medical device intended for the detection of Cytomegalovirus in serum/body fluids.
65.		Herpes simplex virus reagents/kits	Class C	A Herpes simplex virus test reagent/kit is a medical device intended for the detection of Herpes simplex virus in serum/body fluids.
66.		Chlamydia pneumoniae test reagents/kits	Class C	A Chlamydia pneumoniae test reagent/kit is a medical device intended for the detection of Chlamydia pneumonia in serum/body fluids.
67.		Methicillin-Resistant Staphylococcus aureus test reagents/kits	Class C	A Methicillin-Resistant Staphylococcus aureus test reagent/kit is a medical device intended for the detection of Methicillin-Resistant Staphylococcus aureus in serum/body fluids
68.		Enterovirus test reagents/kits	Class C	An Enterovirus test reagent/kit is a medical device intended for the detection of enterovirus) in serum/body fluids.
	Reagents/			
69.	**Kits for detection of Cancer Markers exemplified as :**	Alpha-fetoprotein test reagents/kits	Class C	An Alpha-fetoprotein test reagent/kit is a medical device intended for the detection of Alpha-fetoprotein in serum/body fluids.
70.		Beta-2 microglobulin test reagents/kits	Class C	A Beta-2 microglobulin test reagent/kit is a medical device intended for the detection of Beta-2 microglobulin in serum/body fluids
71.		Bladder tumour antigen (BTA) test reagents/kits	Class C	A Bladder tumour antigen (BTA) test reagent/kit is a medical device intended for the detection of Bladder tumour antigen (BTA)in serum/body fluids

72.		CA15-3 test reagents/kits	Class C	A CA15-3 antigen (BTA) test reagent/kit is a medical device intended for the detection of CA15-3 in serum/body fluids
73.		CA27.29 test reagents/kits	Class C	A CA27.29 test reagent/kit is a medical device intended for the detection of CA27.29 in serum/body fluids
74.		CA125 test reagents/kits	Class C	A CA125test reagent/kit is a medical device intended for the detection of CA125 in serum/body fluids
75.		CA72-4 test reagents/kits	Class C	A CA72-4 test reagent/kit is a medical device intended for the detection of CA72-4 in serum/body fluids
76.		CA19-9 test reagents/kits	Class C	A CA19-9 test reagent/kit is a medical device intended for the detection of CA19-9 in serum/body fluids
77.		Calcitonin test reagents/kits	Class C	A Calcitonin test reagent/kit is a medical device intended for the detection of Calcitonin in serum/body fluids
78.		Carcinoembryonic antigen (CEA) test reagents/kits	Class C	A Carcinoembryonic antigen (CEA) test reagent/kit is a medical device intended for the detection of Carcinoembryonic antigen (CEA) in serum/body fluids
79.		Chromogranin A test reagents/kits	Class C	A Chromogranin A test reagent/kit is a medical device intended for the detection of Chromogranin A in serum/body fluids
80.		Estrogen / Progesterone receptors test reagents/kits	Class C	A Estrogen / Progesterone test reagent/kit is a medical device intended for the detection of Estrogen / Progesterone in serum/body fluids
81.		HER2 (Human Epidermal Growth Factor receptor, test reagents/kits	Class C	A HER2 (Human Epidermal Growth Factor receptor test reagent/kit is a medical device intended for the detection of HER2 (Human Epidermal Growth Factor receptor in serum/body fluids

82.		human Chorionic Goadotropin (hCG) test system test reagents/kits		A human Chorionic Goadotropin (hCG) test reagent/kit is a medical device intended for the detection of human Chorionic Goadotropin (hCG) in serum/body fluids
83.		Lipid associated sialic acid test reagents/kits	Class C	A Lipid associated sialic acid test reagent/kit is a medical device intended for the detection of Lipid associated sialic acid in serum/body fluids
84.		Neuron -Specific Enolase (NSE) test reagents/kits	Class C	A Neuron -Specific Enolase (NSE) test reagent/kit is a medical device intended for the detection of Neuron -Specific Enolase (NSE) in serum/body fluids
85.		NMP22 test reagents/kits	Class C	A NMP22 test reagent/kit is a medical device intended for the detection of NMP22 in serum/body fluids
86.		Prostate-Specific Antigen (PSA) test reagents/kits	Class C	A Prostate-Specific Antigen (PSA) test reagent/kit is a medical device intended for the detection of Prostate-Specific Antigen (PSA) in serum/body fluids
87.		Prostatic Acid Phosphatase (PAP) test reagents/kits	Class C	A Prostatic Acid Phosphatase (PAP) test reagents/kits test reagent/kit is a medical device intended for the detection of Prostatic Acid Phosphatase (PAP) test reagents/kits in serum/body fluids
88.		Prostate Cancer Antigen 3 gene (PCA 3) test reagents/kits	Class C	A Prostate Cancer Antigen 3 gene (PCA 3) test reagent/kit is a medical device intended for the detection of Prostate Cancer Antigen 3 gene (PCA 3) in serum/body fluids
89.		Prostate-Specific Membrane Antigen (PSMA) test reagents/kits	Class C	A Prostate-Specific Membrane Antigen (PSMA) test reagent/kit is a medical device intended for the detection of Prostate-Specific Membrane Antigen (PSMA) in serum/body fluids
90.		S-100 test reagents/kits	Class C	A S-100 test reagent/kit is a medical device intended for the detection of S-100 in serum/body fluids

91.		TA-90 test reagents/kits	Class C	A TA-90 test reagent/kit is a medical device intended for the detection of TA-90 in serum/body fluids
92.		Thyroglobulin test reagents/kits	Class C	A Thyroglobulin test reagent/kit is a medical device intended for the detection of Thyroglobulin in serum/body fluids
93.		Tissue Polypeptide Antigen (TPA) test reagents/kits	Class C	A Tissue Polypeptide Antigen (TPA) test reagent/kit is a medical device intended for the detection of Tissue Polypeptide Antigen (TPA) in serum/body fluids
94.		Other Reagents/ Kits for detection of Cancer Markers	Class **C***	
	Reagents/			
95.	**Kits for estimation of Coagulation parameters exemplified**	PT (Prothrombin Time) test reagents/kits	Class C	A Prothrombin Time (PT)test reagent/kit is a medical device intended for the estimation of prothrombin time in plasma/body fluids.
96.	**as:**	TT (Thrombin Time) test reagents/kits	Class C	A Thrombin Time(TT)test reagent/kit is a medical device intended for the estimation of Thrombin Time in plasma/body fluids
97.		Activated Partial Thromboplastin Time(APTT) testsreagents/kits	Class C	A Activated Partial ThromboplastinTime (APTT) test reagent/kit is a medical device intended for the estimation of Activated Partial ThromboplastinTime in plasma/body fluids
98.		Activated whole blood clotting time tests reagents/kits		A Activated whole blood clotting time test reagent/kit is a medical device intended for the estimation of Activated whole blood clotting Time in plasma/body fluids
99.		Fibrinogen/Fibrin degradation products tests reagents/kits	Class C	A Fibrinogen/Fibrin degradation products test reagent/kit is a medical device intended for the estimation of fibrinogen/fibrin degradation products in plasma/body fluids

100.		D-Dimer tests reagents/kits	Class C	A D-Dimer test reagent/kit is a medical device intended for the estimation of D-Dimer test in plasma/body fluids
101.		Other Reagents/ Kits for estimation of Coagulation parameters	Class **C***	
	Reagents/ Kits for monitoring of drug levels used for therapy or abuse exemplified as under			
102.		Aminoglycoside antibiotics test reagents/kits	Class C	Aminoglycoside antibiotics test reagents/kits are medical devices intended for the estimation of Aminoglycoside antibiotics in serum/body fluids.
103.		Antiepileptics test reagents/kits	Class C	Antiepileptics test reagents/kits are medical devices intended for the estimation of Antiepileptics in serum/body fluids.
104.		Antipsychotics test reagents/kits	Class C	Antipsychotics test reagents/kits are medical devices intended for the estimation of Antipsychotics in serum/body fluids.
105.		Mood stabilisers, test reagents/kits	Class C	Mood stabilisers test reagents/kits are medical devices intended for the estimation of Mood stabilisers in serum/body fluids
106.		Biologic monoclonal antibody drugs test reagents/kits	Class C	Biologic monoclonal antibody drugs test reagents/kits are medical devices intended for the estimation of Biologic monoclonal antibody drugs in serum/body fluids
107.		Buprenorphine (BUP) test reagents/kits	Class C	Buprenorphine (BUP) test reagents/kits are medical devices intended for the estimation of Buprenorphine (BUP) in serum/body fluids
108.		Amphetamine (AMP) test reagents/kits	Class C	Amphetamine (AMP) test reagents/kits are medical devices intended for the estimation of Amphetamine (AMP) in serum/body fluids
109.		Barbiturates (BAR) test reagents/kits	Class C	Barbiturates (BAR) test reagents/kits are medical devices intended for the estimation of Barbiturates (BAR) in serum/body fluids

110.		Opiate test system test reagents/kits	Class C	Opiate test reagents/kits are medical devices intended for the estimation of opiates in serum/body fluids
111.		Benzodiazepines (BZO)Test reagents /kits	Class C	Benzodiazepines (BZO) test reagents/kits are medical devices intended for the estimation of Benzodiazepines (BZO) in serum/body fluids
112.		Cocaine (COC) Test reagents /kits	Class C	Cocaine (COC) test reagents/kits are medical devices intended for the estimation of Cocaine (COC)in serum/body fluids
113.		Cotinine (COT) Test reagents /kits	Class C	Cotinine (COT) test reagents/kits are medical devices intended for the estimation of Cotinine (COT) in serum/body fluids
114.		Ketamine (KET)Test reagents /kits	Class C	Ketamine (KET) test reagents/kits are medical devices intended for the estimation of Ketamine (KET)in serum/body fluids
115.		Ecstasy (MDMA) Test reagents /kits	Class C	Ecstasy (MDMA) test reagents/kits are medical devices intended for the estimation of Ecstasy (MDMA)in serum/body fluids
116.		Methamphetamine (MET)Test reagents /kits	Class C	Methamphetamine (MET) test reagents/kits are medical devices intended for the estimation of Methamphetamine (MET) in serum/body fluids
117.		Morphine (MOP)Test reagents /kits	Class C	Morphine (MOP) test reagents/kits are medical devices intended for the estimation of Morphine (MOP) in serum/body fluids
118.		Methaqualone (MQL)Test reagents /kits	Class C	Methaqualone (MQL) test reagents/kits are medical devices intended for the estimation of Methaqualone (MQL)in serum/body fluids
119.		Methadone (MTD) Test reagents /kits	Class C	Methadone (MTD)test reagents/kits are medical devices intended for the estimation of Methadone (MTD)in serum/body fluids
120.		Oxycodone (OXY)Test reagents /kits	Class C	Oxycodone (OXY) test reagents/kits are medical devices intended for the estimation of Oxycodone (OXY) in

				serum/body fluids
121.		Phencyclidine (PCP) Test reagents /kits	Class C	Phencyclidine (PCP) test reagents/kits are medical devices intended for the estimation of Phencyclidine (PCP)in serum/body fluids
122.		Propoxyphene (PPX) Test reagents /kits	Class C	Propoxyphene (PPX) test reagents/kits are medical devices intended for the estimation of Propoxyphene (PPX) in serum/body fluids
123.		Tricyclic Antidepressants (TCA)Test reagents /kits	Class C	Tricyclic Antidepressants (TCA) test reagents/kits are medical devices intended for the estimation of Tricyclic Antidepressants (TCA) in serum/body fluids
124.		Marijuana (THC)Test reagents /kits	Class C	Marijuana (THC) test reagents/kits are medical devices intended for the estimation of Marijuana (THC) in serum/body fluids
125.		Tramadol (TRA) Test reagents /kits	Class C	Tramadol (TRA) test reagents/kits are medical devices intended for the estimation of Tramadol (TRA) in serum/body fluids
126.		Fentanyl (FEN)Test reagents /kits	Class C	Fentanyl (FEN) test reagents/kits are medical devices intended for the estimation of Fentanyl (FEN) in serum/body fluids
127.		Methadone Metabolite (EDDP)Test reagents /kits	Class C	Methadone Metabolite (EDDP) test reagents/kits are medical devices intended for the estimation of Methadone Metabolite (EDDP)in serum/body fluids
128.		Other Reagents/ Kits for monitoring of drug levels used for therapy or abuse	Class **C***	
	Reagents/			
129.	**Kits for detection of autoimmune disorders exemplified as:**	Anti Nuclear Antibodies test reagents/kits	Class B	Anti Nuclear Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to nuclear antigens in human specimens.

130.		Anti Transglutaminase Antibodies test reagents/kits	Class B	Anti Transglutaminase Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to Transglutaminase in human specimens.
131.		Anti Ganglioside Antibodies test reagents/kits	Class B	Anti Ganglioside Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to Ganglioside in human specimens
132.		Anti-Cyclic Citrullinated Peptide (CCP) Antibodies test reagents/kits	Class B	Anti CyclicCitrullinated Peptide (CCP) Antibodies test reagent/kit is a medical device for the screening of CCP auto-antibodies in human specimens.
133.		Rheumatoid Factor (RF) immunological test reagents/kits	Class B	Rheumatoid Factor (RF) immunological test reagent/kit is a medical device for the screening of Rheumatoid Factor in human specimens.
134.		Anti Smooth Muscle Antibody test reagents/kits	Class B	Anti Smooth Muscle Antibody test reagent/kit is a medical device for the screening of auto-antibodies to smooth muscles in human specimens.
135.		Glutamic Acid Decarboxylase (GAD) Antibody test reagents/kits	Class B	Glutamic Acid Decarboxylase (GAD) Antibodytest reagent/kit is a medical device for the screening of auto-antibodies to Glutamic Acid Decarboxylase (in human specimens
136.		Anti ovary antibodies test reagents/kits	Class B	Anti ovary antibodies test reagent/kit is a medical device for the screening of auto-antibodies to ovarian antigens in human specimens
137.		Anti sperm Antibodies test reagents/kits	Class B	Anti sperm antibodies test reagent/kit is a medical device for the screening of auto-antibodies to spermatozoa in human specimens.
138.		Anti-IA2 test reagents/kits	Class B	Anti IA-2 antibodies test reagent/kit is a medical device for the screening of auto-antibodies to IA-2 (tyrosine phosphatase) in human specimens

139.		Anti-Acetylcholine Receptor test reagents/kits	Class B	Anti-Acetylcholine Receptor test reagent/kit is a medical device for the screening of auto-antibodies to Acetylcholine Receptor in human specimens
140.		Anti Thyroid gland antibody test reagents/kits	Class B	Anti Thyroid gland antibodies test reagent/kit is a medical device for the screening of auto-antibodies to thyroid gland antigens in human specimens
141.		ANCA test reagents/kits	Class B	The ANCA test reagent/kit is a medical device for the screening of Anti-Neutrophil Cytoplasmic Antibodies (ANCA) in human specimens .
142.		Anti-double stranded DNA (anti-dsDNA)test reagents/kits	Class B	The Anti-double stranded DNA (Anti-dsDNA) test reagent/kit is a medical device for the screening of auto-antibodies to Double stranded DNA in human specimens
143.		Anti-Extractable Nuclear Antigen(Anti-ENA)test reagents/kits	Class B	The Anti-Extractable Nuclear Antigen(Anti-ENA)test reagent/kit is a medical device for the screening of auto-antibodies to Extractable Nuclear Antigens like Smith (Sm) Antigens, Ribonuclears Protein (RNP), anti SSA (Ro) etc. in human specimens.
144.		Anti-Intrinsic Factor test reagents/kits	Class B	The Anti-Intrinsic Factor test reagent/kit is a medical device for the screening of antibodies against intrinsic factor in human specimens.
145.		Anti-*Saccharomyces Cerevisiae* Antibodies (ASCA) test reagents/kits	Class B	The Anti-Saccharomyces Cerevisiae Antibodies (ASCA) test reagent/kit is a medical device for the screening of antibodies against Saccharomyces Cerevisiae in human specimens.
146.		Other Reagents/ Kits for detection of autoimmune disorders	**Class B***	
147.	**Reagents/**			

148.	**Kits for detection of markers for Congenital disorders exemplified as under**	Triple Screen Test reagents/kits for Down's Syndrome	Class C	Triple Screen Test reagent/kit for Down's Syndrome is a medical device intended for the screening of Down's Syndrome in serum/plasma.
149.		Quadruple Screen Test reagents/kits for Down's Syndrome	Class C	Quadruple Screen Test reagent/kit for Down's Syndrome is a medical device intended for the screening of Down's Syndrome in serum/plasma
150.		Chorionic Villus Sample Test reagents/kits for Down's Syndrome	Class C	Chorionic Villus Sample Test reagent/kit for Down's Syndrome is a medical device intended for the detection of Down's Syndrome in body fluids.
151.		Maternal Serum Alpha-Fetoprotein (MSAFP) test reagents/kits for spina bifida	Class C	Maternal Serum Alpha-Fetoprotein (MSAFP) Test reagents/kits for is a medical device intended for the screening of spina bifida in serum.
152.		Others Reagents/ Kits for detection of Congenital disorders	Class **C***	
	Reagents/			
153.	**Kits for detection of Cardiac Markers exemplified as under**	Creatine Kinase (CK) and CKMB test reagents/kits	Class B	Creatine Kinase (CK) and CKMB test reagent/kit are medical devices intended for the estimation of Creatine Kinase (CK) and CKMB in blood / body fluids.
154.		Myoglobin test reagents/kits	Class B	Myglobin Test reagent/kit for is a medical device intended for the estimation of myglobin in blood /body fluids.
155.		Troponin test reagents/kits	Class C	A Troponin test reagent/kit for near patient testing, is a medical device intended for the estimation of Troponin T,I and its variants in blood /body fluids
156.		BNP &NT pro BNP test reagents/kits	Class C	BNP &NT pro BNP Test reagent/kit for is a medical device intended for theestimation of BNP &NT pro BNP in blood / body fluids
	Reagents/			
157.	**Kits for human Genetic testing**	Genetic test reagents/kits for Cystic Fibrosis	Class C	Genetic test reagent/kit for Cystic Fibrosis is a medical device intended for the detection of Cystic Fibrosis in human specimens.

158.	**exemplified as:**	Genetic test for Huntington's chorea	Class C	Genetic test reagent/kit for Huntington's chorea is a medical device intended for the detection of Huntington's chorea in human specimens.
159.		Other Reagents/ Kits for human Genetic testing	Class **C***	
	Reagents/ Kits for the management of life threatening infections exemplified as under:			
160.		HIV Viral Load test reagents/kits	Class C	HIV Viral Load test reagent/kit is a medical device intended for the estimation of HIV Viral Load in blood/body fluids.
161.		HBV Viral Load test reagents/kits	Class C	HBV Viral Load test reagent/kit is a medical device intended for the estimation of HBV Viral Load in blood/body fluids.
162.		HCV Viral Load test reagents/kits	Class C	HCV Viral Load test reagent/kit is a medical device intended for the estimation of HCV Viral Load in blood/body fluids.
163.		CD4 Count & % test reagents/kits	Class C	CD4 Count & % test reagent/kit is a medical device intended for the estimation of CD4 Count & % in blood/body fluids.
164.		CD8 Count & % test reagents/kits	Class C	CD8 Count & % test reagent/kit is a medical device intended for the estimation of CD8 Count & % in blood/body fluids.
165.		CD4/CD8 Ratio test reagents/kits	Class C	CD4/CD8 Ratio test reagent/kit are a medical device intended for the estimation of CD4/CD8 Ratio in blood/body fluids.
166.		Other Reagents/ Kits for the management of life threatening infections	Class **C***	
	Reagents/ Kits for the detection of sexually transmitted			
167.		Treponema pallidum test reagents and kits	Class C	Treponema pallidum test reagent/kit is a medical device intended for the detection of Treponema pallidum in blood/body fluids.

168.	**agent exemplified as under:**	Neisseria gonorrhoeae test reagents and kits	Class C	Neisseria gonorrhoeae test reagent/kit is a medical device intended for the detection of Neisseria gonorrhoeae in blood/body fluids
169.		Human Papilloma Virus (HPV) test reagents and kits	Class C	Human Papilloma Virus (HPV) test reagent/kit is a medical device intended for the detection of Human Papilloma Virus in blood/body fluids
170.		Chlamydia test reagents and kits	Class C	Chlamydia test reagent/kit is a medical device intended for the detection of Chlamydia in blood/body fluids
171.		Herpes Virus test reagents and kits	Class C	Herpes Virus test reagent/kit is a medical device intended for the detection of Herpes Virus in blood/body fluids
172.		Other Reagents/ Kits for the detection of sexually transmitted agent	Class **C***	
173.	**Reagents/ Kits for the Antigen detection of infectious agents with a risk of limited propagation exemplified as:**			
174.		Malaria Antigen test reagents and kits	Class C	Malaria Antigen test reagent/kit is a medical device intended for the detection of Malaria Antigen in blood/body fluids
175.		Dengue virus Antigen test reagents and kits	Class C	Dengue virus Antigen test reagent/kit is a medical device intended for the detection of Dengue virus Antigen in blood/body fluids
176.		Chikungunya Antigen test reagents and kits	Class C	Chikungunya Antigen test reagent/kit is a medical device intended for the detection Chikungunya Antigen of in blood/body fluids
177.		Leptospira Antigen test reagents and kits	Class C	Leptospira Antigen test reagent/kit is a medical device intended for the detection of Leptospira Antigen in blood/body fluids
178.		Japanese Encephalitis Antigen test reagents and kits	Class C	Japanese Encephalitis Antigen test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antigen in blood/body fluids

179.		Typhoid Antigens test reagents and kits	Class C	Typhoid Antigens Test reagent/kit is a medical device intended for the detection of Typhoid Antigens in blood/body fluids
180.		Influenza A Antigen test reagents and kits	Class C	Influenza A Antigen test reagent/kit is a medical device intended for the detection of Influenza A Antigen in blood/body fluids
181.		Influenza B Antigen test reagents and kits	Class C	Influenza B Antigen test reagent/kit is a medical device intended for the detection of Influenza B Antigen in blood/body fluids
182.		Strep A Antigen test reagents and kits	Class C	Strep A Antigen test reagent/kit is a medical device intended for the detection of Strep A Antigen in blood/body fluids
183.		Strep B Antigen test reagents and kits	Class C	Strep B test Antigen reagent/kit is a medical device intended for the detection of Strep B Antigen in blood/body fluids
184.		Chagas Antigen test reagents and kits	Class C	Chagas disease Antigen test reagent/kit is a medical device intended for the detection of Chagas disease Antigen in blood/body fluids
185.		Filariasis Antigen test reagents and kits	Class C	Filariasis test Antigen reagent/kit is a medical device intended for the detection of Filariasis Antigen in blood/body fluids
186.		Kala Azar Antigen test reagents and kits gen	Class C	Kala Azar Antigen test reagent/kit is a medical device intended for the detection of Kala Azar Antigen in blood/body fluids
187.		Rotavirus Antigen test reagents and kits	Class C	Rotavirus Antigen test reagent/kit is a medical device intended for the detection of Rotavirus Antigen in blood/body fluids
188.		S. pneumonia Antigen test reagents and kits	Class C	S. pneumonia Antigen test reagent/kit is a medical device intended for the detection of S. pneumonia Antigen in blood/body fluids
189.		H. pylori Antigen Antigen test reagents and kits Antigen	Class C	H. pylori Antigen test reagent/kit is a medical device intended for the detection of H. pylori Antigen in blood/body fluids

190.		Other Reagents/ Kits for the detection of infectious agents with a risk of limited propagation	Class **C***	Reagents/ Kits, other than above, for the Antigen detection of infectious agents with a risk of limited propagation
191.	**Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation exemplified as under**			
192.		Malaria Antibody test reagents and kits	Class B	Malaria Antibody test reagent/kit is a medical device intended for the detection of Malaria Antibody in blood/body fluids
193.		Dengue Antibody test reagents and kits	Class B	Dengue Antibody test reagent/kit is a medical device intended for the detection of Dengue Antibody in blood/body fluids
194.		Chikungunya Antibody test reagents and kits	Class B	Chikungunya Antibody test reagent/kit is a medical device intended for the detection of Chikungunya Antibody in blood/body fluids
195.		Leptospira Antibody test reagents and kits	Class B	Leptospira Antibody test reagent/kit is a medical device intended for the detection of Leptospira Antibody in blood/body fluids
196.		Japanese Encephalitis Antibody test reagents and kits	Class B	Japanese Encephalitis Antibody test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antibody in blood/body fluids
197.		Typhoid Antibody test reagents and kits	Class B	Typhoid Antibody test reagent/kit is a medical device intended for the detection of Typhoid Antibody in blood/body fluids

198.		Cryptococcus neoformans Antibody test reagents and kits	Class B	Cryptococcus neoformans Antibody test reagent/kit is a medical device intended for the detection of Cryptococcus neoformans Antibody in blood/body fluids
199.		Neisseria meningitides Antibody test reagents and kits	Class B	Neisseria meningitides Antibody test reagent/kit is a medical device intended for the detection of Neisseria meningitides Antibody in blood/body fluids
200.		Vibrio cholera Antibody test reagents and kits	Class B	Vibrio cholera Antibody test reagent/kit is a medical device intended for the detection of Vibrio cholera Antibody in blood/body fluids
201.		Influenza A Antibody test reagents and kits	Class B	Influenza A Antibody test reagent/kit is a medical device intended for the detection of Influenza A Antibody in blood/body fluids
202.		Influenza B Antibody test reagents and kits	Class B	Influenza B Antibody test reagent/kit is a medical device intended for the detection of Influenza B Antibody in blood/body fluids
203.		Strep A Antibody test reagents and kits	Class B	Strep A Antibody test reagent/kit is a medical device intended for the detection of Strep A Antibody in blood/body fluids
204.		Strep B Antibody test reagents and kits	Class B	Strep B Antibody test reagents/kits is a medical device intended for the detection of Strep B Antibody in blood/body fluids
205.		Chagas Antibody test reagents and kits	Class B	Chagas Antibody test reagent/kit is a medical device intended for the detection of Chagas Antibody in blood/body fluids
206.		Filariasis Antibody test reagents and kits	Class B	Filariasis Antibody test reagent/kit is a medical device intended for the detection of Filariasis Antibody in blood/body fluids
207.		Kala Azar Antibody test reagents and kits	Class B	Kala Azar Antibody test reagents/kits is a medical device intended for the detection of Kala Azar Antibody in blood/body fluids

208.		Rotavirus Antibody test reagents and kits	Class B	Rotavirus Antibody test reagents/kits is a medical device intended for thedetection of Rotavirus Antibody in blood/body fluids
209.		S. pneumonia Antibody test reagents and kits	Class B	S. pneumonia Antibody test reagent/kit is a medical device intended for the detection of S. pneumonia Antibody in blood/body fluids
210.		H. pylori Antibody test reagents and kits	Class B	H.pylori Antibody test reagent/kit is a medical device intended for the detection of H.pylori Antibody in blood/body fluids
211.		Other Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation	**Class B***	
	In vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing			
212.		All other than, the ABO system; the Duffy system; the Kell system; the Kidd system; the Rhesus system, test reagents/kits.	Class C	
213.		ABO System test reagents/kits	Class D	Intended for blood grouping or tissue typing.
214.	**in vitro Diagnostic Medical**	Rhesus (D) System test reagents/kits	Class D	

215.	**Devices for Blood Grouping or Tissue Typing**	The Duffy system test reagents/kits	Class D	
216.		The Kell system test reagents/kits	Class D	
217.		The Kidd system test reagents/kits	Class D	
218.		HLA test reagents/kits	Class D	.
	Reagents/ Kits for the detection of transmissible agents - screening & confirmatory			
219.		HIV test reagents/kits	Class D	HIV test reagents/kits is a medical device intended for the detection of HIV in blood/body fluids.
220.		HBV test reagents/kits	Class D	HBV test reagents/kits is a medical device intended for the detection of HBV in blood/body fluids
221.		HCV test reagents/kits	Class D	HCV test reagents/kits is a medical device intended for the detection of HCV in blood/body fluids
222.		Syphilis screening reagents/kits	Class D	Syphilis test reagents/kits is a medical device intended for the screening of Syphilis in blood/body fluids
223.		Malaria screening reagents/kits	Class D	Malaria test reagents/kits is a medical device intended for the screening of Malaria in blood/body fluids
	Other in vitro Medical Devices			
224.		TSH test reagents/kits	Class B	TSH test reagent/kit is a medical device intended for the estimation TSH in blood/body fluids.
225.		Total /Free triiodothyronine (T3) test reagents/kits	Class B	Total /Free triiodothyronine (T3) test reagent/kit is a medical device intended for the estimation Total /Free triiodothyronine (T3) in blood/body fluids
226.		Total / Free thyroxine (T4) test reagents/kits	Class B	Total / Free thyroxine (T4)test reagent/kit is a medical device intended for the estimation of Total / Free thyroxine (T4)in blood/body

				fluids
227.		Dehydroepiandrosterone (DHEA-S) (free and sulfate) test reagents/kits	Class B	Dehydroepiandrosterone (DHEA-S) (free and sulfate) test reagent/kit is a medical device intended for the estimation of DHEA-S (free and sulfate) in blood/body fluids
228.		Estrogen test reagents/kits	Class B	Estrogen test reagent/kit is a medical device intended for the estimation of Estrogen in blood/body fluids
229.		Progesterone test reagents/kits	Class B	Progesterone test reagent/kit is a medical device intended for the estimation of Progesterone in blood/body fluids
230.		Testosterone (Free and Total) test reagents/kits	Class B	Testosterone (Free and Total) test reagent/kit is a medical device intended for the estimation of Testosterone (Free and Total) in blood/body fluids
231.		Sex Hormone Binding Globulin (SHBG) test reagents/kits	Class B	Sex Hormone Binding Globulin (SHBG) test reagent/kit is a medical device intended for the estimation of Sex Hormone Binding Globulin (SHBG) in blood/body fluids
232.		Cortisol test reagents/kits	Class B	Cortisol test reagent/kit is a medical device intended for the estimation of Cortisol in blood/body fluids
233.		Insulin test reagents/kits	Class B	Insulin test reagent/kit is a medical device intended for the estimation of Insulin in blood/body fluids
234.		Luteinizing Hormone(LH) test reagents/kits	Class B	Luteinizing Hormones(LH)test reagent/kit is a medical device intended for the estimation of Luteinizing Hormone (LH) in blood/body fluids
235.		Follicle Stimulating Hormone(FSH) test reagents/kits	Class B	Follicle Stimulating Hormone (FSH) test reagent/kit is a medical device intended for the estimation of Follicle Stimulating Hormone(FSH) in blood/body fluids
236.		Prolactin test reagents/kits	Class B	Prolactin test reagent/kit is a medical device intended for the estimation of Prolactin in blood/body fluids

237.		Other test reagents/kits for hormones	Class B	Test reagents/kits for the estimation of other than above hormones in blood/body fluids
238.		Vitamin B test reagents/kits	Class B	Vitamin B test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids
239.		Vitamin D test reagents/kits	Class B	Vitamin D test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids
240.		Vitamin A test reagents/kits	Class B	Vitamin A test reagent/kit is a medical device intended for the estimation of Vitamin A in blood/body fluids
241.		Vitamin E test reagents/kits	Class B	Vitamin E test reagent/kit is a medical device intended for the estimation of Vitamin E in blood/body fluids
242.		Vitamin K test reagents/kits	Class B	Vitamin K test reagent/kit is a medical device intended for the estimation of Vitamin K in blood/body fluids
243.		Other test reagents/kits for vitamins	Class B	Test reagents/kits for the estimation of other than above vitamins in blood/body fluids
244.		Homocystein test reagents/kits	Class B	Homocystein test reagent/kit is a medical device intended for the estimation of Homocystein in blood/body fluids
245.		allergens test reagents/kits	Class B	Test reagents/kits intended for the estimation of allergens in blood/body fluids
246.	calibrators/controls for above all in vitro diagnostic medical devices	Calibrators	-	Calibrators intended to be used with a reagent should be treated in the same class as the In vitro diagnostic medical device reagent.
247.		Controls	-	Controls intended to be used with a reagent should be treated in the same class as the In vitro diagnostic medical device reagent

Note: Anticoagulant Solutions, Embolization Particles, chitosan scaffold (for cartilage repair), Riboflavin (for Corneal Collagen cross-linking), silicone oil endotamponade, Intraocular Gases and Injectable Fillers shall be regulated as drugs under the provisions of the Drugs and Cosmetics Act, and Drugs and Cosmetics Rules, 1945.

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Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

File No. 29/Misc/3/2017-DC (292) **Date: 15.05.2019**

Notice

Classification of newly notified Medical Devices

S. No.	Notified Category	Intended Use	Risk Class
1.	CT scan Equipment	Use of x-ray source and digitally scanned computer technology to create cross-sectional images of the body.	Class C
2.	MRI Equipment	It is a medical imaging procedure using radio waves, magnetic fields, and magnetic field gradients to generate images of organs in the body.	Class C
3.	Defibrillators	It is a device that automatically analyzes the rhythm of heart of cardiac arrest patients and delivers an electrical shock to the heart for restoring the normal rhythm of heart.	Class C
4.	Dialysis Machine	It is used for acute or chronic kidney failure that filters blood to remove excess water and waste products.	Class C
5.	PET Equipment	Intended to detect the gamma radiation and positron emitting radionuclides in the body and produce cross-sectional images which reflect the distribution in the body or individual organs.	Class C
6.	X-Ray Machine	Use of X-rays to diagnose or treat patients by imaging the internal structure of the body to assess the abnormalities in the body.	Class C
7.	Bone marrow cell separator	It is a general lab equipment to be used to isolate target cells and cells concentrate from bone and blood.	Class B

8.	**Nebulizer**	It is device used to administer medications in the form of mist to inhale for respiratory disorders.	**Class C**
9.	**Blood Pressure Monitoring Devices**	It is device used to measure the diastolic and systolic blood pressures.	**Class B**
10.	**Digital Thermometer**	It is device used to record the body temperature.	**Class B**
11.	***Glucometer**	It is a device used to measure the concentration of glucose in blood.	**Class C**
12.	**Organ Preservative Solution**	Solution for hypothermic flushing, storage and transport of organs and to maintain the organ vitality during transplant into human recipients.	**Class C**

*** Glucometer will be regulated under IVD category**

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (177) Date: 12 JUL 2021

Subject: Classification of medical devices pertaining to Anesthesiology under the provisions of Medical Devices Rules, 2017-Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.1.2017 which are to be commence from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices, Appendix A, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A is subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V.G. Somani)
Drugs Controller General (I)

To,

CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC(177)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

Date:

Notice

Classification of Medical Devices Pertaining to Anesthesiology

Sr. No	Medical Device Name	Intended Use	Risk Class
1	Anesthesia machine	A medical device used to generate and mix a fresh gas flow of medical gases and inhalational anaesthetic agents for the purpose of inducing,monitoring and maintaining anaesthesia.	C
2	Aerosol delivery tubing	A flexible tube used in conjunction with an oxygen mask, endotracheal (ET) tube, humidifier, or nebulizer, intended for the delivery of aerosolized humidification, typically oxygen enriched.	A
3	Aerosol face mask	A flexible, form-shaped device that is placed over the nose and mouth to deliver air, oxygen (O2), or a mixture of the two gases, with aerosolized particles, to a patient's airway.	B
4	Aerosol inhalation monitor	It is a device that enables a medical professional to objectively assess in detail how the test subject uses their inhaler.	B
5	Airway device cleaning utensil	A hand-held device intended to be used to clean an in situ and ex situ airway device.	A
6	Airway pressure alarm	A device connected to the breathing circuit that monitors a patient's upper airway pressure during assisted mechanical ventilation.	A
7	Airway pressure/oxygen monitor	It is a device intended to continuously measure and display the breathing circuit pressure and oxygen (O2) concentration levels of respiratory gases delivered to a patient through positive pressure ventilation systems.	B
8	Airway protection face mask	A flexible, form-shaped device that is placed over the nose and mouth to provide respiratory protection.	A
9	Airway temperature monitoring system	An assembly of devices used to continuously measure the temperature at a specific point along a ventilation airway.	B
10	Airway tube forceps	A hand-held instrument used for grasping a tube for its insertion and/or extraction into/from the airways, or for grasping obstructive objects for their removal from the airways.	A
11	Anaesthesia breathing circuit	An assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient.	B

12	Anaesthesia catheter Luer connector	It is a device intended to create a mechanical union between an anaesthesia catheter and an external device, via a Luer connection.	A
13	Anaesthesia depth monitor	It is a device intended to be used to detect, process, and display the signals recorded from an unconscious patient (in a state of anaesthesia), showing the degree of consciousness.	B
14	Anaesthesia depth simulator	A device intended to simulate the electroencephalography (EEG) signals of an unconscious patient (in a state of anaesthesia) in order to test and calibrate an anaesthesia depth monitor, check patient cable continuity, or train healthcare providers.	A
15	Anaesthesia instrument table	It is intended as a support for Anaesthesia instruments used during general anaesthesia surgical procedures.	A
16	Anaesthesia mask stabilizer	A device intended to secure an anaesthesia mask on the face of a patient typically by providing anchorage for the fixation of the mask's headstrap.	A
17	Anaesthesia system leakage tester	A device intended to test an anaesthesia system for leakage.	A
18	anaesthesia vaporizer	A device used to vaporize the anaesthetic agent and deliver a controlled amount of the agent to a patient being prepared for surgery.	C
19	Anaesthesia warmer	A device intended to warm the anaesthetic solutions prior to it being administered to a patient for anaesthesia.	A
20	Anaesthesia workstation gas scavenger	A device intended to connect between the expiratory valve/port of a breathing circuit and the extraction system enabling the waste anaesthetic, exhaled, or other trace gases to be removed under controlled conditions from the work environment and channelled to the outside of the building.	B
21	Anaesthetic gas absorption/desorption device	A device intended to, when integrated within the common line of a breathing circuit, absorb and desorb (i.e., recycle) exhaled volatile anaesthetic agents.	B
22	Anaesthetic gas scavenging terminal unit	A device intended to function as an outlet assembly to which the operator can connect/disconnect an anaesthetic gas scavenging system (AGSS).	A
23	Anesthesia Face Mask	A device designed to be placed over a patient's nose and/or mouth to administer anaesthetic gases to the upper airway.	A
24	Artificial airway stylet	A device intended for insertion within the lumen of an artificial airway tube to stiffen and/or maintain the shape of the tube to facilitate intubation.	A
25	Artificial airway washing/disinfection jar	A container intended to hold artificial airway devices to facilitate their washing/disinfection.	B
26	Atomizer	A device that is intended to provide liquid medication in aerosolized form into the air that a patient will breathe.	A

27	Brachial plexus anaesthesia kit	A collection of devices intended to deliver a brachial plexus nerve block through one of several routes that could include supraclavicular, interscalene, infraclavicular, or axillary.	B
28	Breathing circuit bag	A device intended to store breathing gas during the respiratory cycle.	A
29	Breathing circuit condenser	A device intended to be integrated within the expiratory limb of a breathing circuit to remove excess moisture through cooling and condensing, whilst also reheating the dried gases to an appropriate machine-compatible temperature.	A
30	Breathing circuit dryer	A device that is used for the purpose of drying breathing circuit equipment that have been washed inorder to prevent bacteria growth and deterioration	A
31	Breathing circuit gas-sampling/monitoring set	A collection of devices intended to be integrated within a breathing circuit to enable interface of gases between the breathing circuit and a respiratory monitoring device for sampling the patient's expired gas for measurements of pressure, flow and/or gas analysis.	B
32	Breathing circuit washer/disinfector	A device intended for the cleaning and high-level disinfection of breathing circuit components used in respiratory therapy and anaesthesia equipment.	B
33	Breathing mouthpiece	A device intended to be inserted into a patient's mouth to facilitate access to the respiratory system.	A
34	Bronchoscope	An endoscope with an inserted portion intended for the visual examination and treatment of the trachea, primary bronchi, and upper regions of the lungs and take biopsies and sample of secretions.	A
35	Capnography oxygen mask	A device intended to be placed over the nose and mouth to deliver oxygen (O2) to a patient's airway and to sample exhaled respiratory gases for monitoring the patient’s ventilatory status.	A
36	Capnography sampling adaptor	The device is intended for sampling CO2 and use with monitors enabled with capnography technology .	A
37	Carbon dioxide monitor	A device intended to continuously measure the concentration of carbon dioxide (CO2) in a gas mixture to determine a patient's ventilatory, circulatory, or metabolic status.	C
38	CPAP/BPAP nasal mask	A device designed to be placed over a user's nose to interface with a continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP) unit to provide the respiratory tract with direct ambient air, or medical oxygen (O2) and air, at a higher pressure than ambient air for noninvasive positive pressure ventilation (NPPV).	B

39	CPAP/BPAP oral mask	A device designed to be fitted to the user's mouth to interface with a continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP) unit to provide the respiratory tract with direct ambient air, or medical oxygen (O2) and air, at a higher pressure than ambient air for noninvasive positive pressure ventilation (NPPV).	B
40	Electronic epidural space locator control unit	A device intended to be used with an epidural needle and an electronic epidural space locator pressure-sensing set, to aid a user in locating the epidural needle tip within the epidural space for subsequent anaesthesia administration.	D
41	Electronic oesophageal stethoscope	An electronic listening device designed to be inserted into a patient's oesophagus to listen to heart and breathe sounds, typically while the patient is under anaesthesia.	B
42	Endobronchial airway sizing kit	A collection of mechanical devices intended to be used with a balloon catheter for a planned intervention to determine the appropriate endobronchial valve sizes for a patient's lung airways (bronchial lumens).	A
43	Helium/oxygen breathing gas mixer	An independent mechanical device designed for accurate mixing of helium (He) and oxygen (O2) with concentrations that are appropriated for breathing in a patient who is indicated to assist flow of O2 into the alveoli and to reduce the work of breathing.	B
44	High-frequency ventilator	A device intended to assist or control alveolar ventilation using a frequency that is considerably higher than the physiological breathing rate and a tidal volume less than or equal to the anatomic dead space.	C
45	Inhalational analgesia unit	A device primarily designed to administer analgesic gases to the patient, or produce analgesic vapours for inhalation.	B
46	In-line arterial blood sampling set	A collection of devices designed to obtain an in-line arterial blood specimen while maintaining a closed system.	A
47	In-line backflow valve	A general-purpose device used in medical tubing or pipe-lines to prevent the backflow of gases or liquids.	A
48	Intracardiac oximeter	A photoelectric device designed to transmit radiation at a known wavelength(s) through blood to measure the concentration of oxygen, or dye, within the heart based on the amount of reflected or scattered radiation.	B
49	Intravascular blood gas/pH monitoring system	An assembly of devices used for the continuous in vivo measurement and display of the values of pH and/or the partial pressure of CO2 and/or O2 in arterial blood. The system is used for patients with respiratory failure or severe pulmonary hypertension after cardiac surgery.	B

50	Intravascular membrane oxygenator	A device designed for intravascular diffusion of oxygen into and carbon dioxide from the blood across an implantable (vena cava) gas-permeable membrane, used mainly as a temporary treatment for failing lungs in adults with respiratory distress syndrome.	C
51	Intravascular oximeter	An instrument designed for the continuous in vivo measurement of venous blood oxygen saturation (SvO2) using a fibreoptic catheter.	B
52	Intubation laryngoscope	A hand-held device intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.	A
53	Intubation teeth protector	A device designed to fit over the upper and lower sets of teeth to protect them from damage during endotracheal (ET) tube intubation procedures.	A
54	Invasive arterial pressure cardiac output/oximetry monitor	A device intended to continuously measure and display arterial pressure cardiac output (APCO) and haemoglobin oxygen saturation (e.g., SpO2) when connected to an extravascular blood pressure transducer linked to a peripheral arterial line, and to a pulse oximeter or an oximetry catheter.	B
55	Laryngeal airway introducer	A device intended to aid insertion of a laryngeal airway into the pharyngeal cavity of a patient while reducing or eliminating the need for finger manipulation within the mouth. It is typically in the form of a metal blade with a handle and may be mounted onto the laryngeal airway during insertion. This is a reusable device intended to be sterilized prior to use.	A
56	Laryngectomy tube	A device intended to maintain tracheostoma patency after laryngectomy to provide an airway for the patient and to prevent tracheostomal stenosis in the months following the procedure.	B
57	Laryngotracheal anaesthesia applicator	A non-sterile container that is prefilled with an anaesthetic agent and intended to be used to apply the agent to the oropharynx and upper airway, to relax laryngotracheal reflexes prior to an intervention of an endotracheal (ET) tube or other type of tracheal tube.	B
58	Manual jet ventilation device	A portable, manually-operated, noninvasive device intended to be used in conjunction with a separate compressed oxygen (O2) source and airway access device for transtracheal ventilation of a patient in an emergency situation where there is complete or partial obstruction of the airways.	C

59	Mechanical positive pressure airway secretion-clearing device	A hand-held, mechanical device designed to remove excessive mucus or sputum (phlegm) from the lungs and upper airway of a patient typically suffering from acute or chronic lung disease.	A
60	Medical gas flowmeter	A device intended to measure and regulate the flow of a medical gas during various procedures.	A
61	Medical gas flowmeter, Thorpe tube	A device intended to measure and regulate the flow of a medical gas during various procedures.	A
62	Medical gas pipeline system	An assembly of devices designed to supply compressed medical gases from a central source to endpoints throughout a medical facility.	A
63	Medical gas pipeline system automatic outlet analyser	A mains component of a medical gas pipeline supply system that monitors the composition of a gas delivered from the supply system.	A
64	Medical gas pipeline system pressure monitor	A component of a medical gas pipeline system designed to continuously monitor and detect changes in the pressure values of the medical gases in the supply pipeline.	A
65	Medical gas terminal unit	A device that is a component of a medical gas pipeline system or a medical gas/vacuum pipeline system that has a gas-specific outlet connection for a single/mixture of gas to which the operator can connect and disconnect a medica device.	A
66	Microbial medical gas filter	A screening device intended to remove microbes from medical gases to prevent patient exposure during respiration, anaesthesia and/or endoscopy.	B
67	Negative-pressure ventilator	An automatic cycling machine used to assist or control alveolar respiration that exerts a negative pressure on the external surface of the chest wall, expanding the chest and moving air into the lungs.	C
68	Neonatal chest percussor	A hand-held device (a percussor) intended to be operated by a healthcare professional to provide external vibrations to the chest wall of a neonate to help loosen bronchial mucus for expectoration through suctioning. It is used to help loosen secretion build-up in the lungs of neonates who cannot perform the natural cough mechanism.	B
69	Nerve-block injection manometer	A noninvasive device intended to be connected between a syringe and a nerve-block needle to indicate injection pressure during administration of local or regional anaesthesia to achieve peripheral nerve blockade.	A
70	Nitric oxide delivery unit	A device intended for the delivery of precise amounts of nitric oxide (NO), also known as nitrogen monoxide, to the respiratory tract of neonate, paediatric, and adult patients to treat severe respiratory disorders.	B

71	Non-heated respiratory humidifier	A device designed to prevent the drying of airway passages associated with the inhalation of oxygen (O2) by adding water vapour to the dry gas as it is passed through, or more seldom, over water.	B
72	Non-rebreathing oxygen face mask	A flexible, form-shaped device designed with valve to control rebreathing and contamination of gas, placed over the nose and mouth to deliver air of high oxygen (O2) concentration to a patient's airway for oxygen therapy.	A
73	Nose clip	A device intended to be used to compress the nose externally, to ensure that airflow is exclusively conducted through the mouth during examinations of the pulmonary function and/or to stop nosebleeds.	A
74	Oxygen administration hood	A device consisting of a rigid transparent plastic shell forming an enclosure over the head of an adult, typically to provide an enriched oxygen (O2)environment to increase the patient's O2 uptake.	A
75	Oxygen saturation/pulse rate simulator	An electronic instrument designed to simulate arterial oxygen saturation and/or pulse rate for testing and calibrating pulse oximeters, pulse oximeter probes and other related pulse oximetry devices.	A
76	Oxygen/air breathing gas mixer	A portable mechanical device designed to mix air and oxygen (O2) for mobile O2 administration during first aid or emergency situations.	B
77	Patient physiologic monitoring system	An assembly of devices designed for continuous assessment of several vital physiologic parameters of patient(s).	C
78	Pleural manometer	A noninvasive device intended to convert pressure into electrical signals for the measurement of pressure within the pleural cavity.	B
79	Pneumatic chest percussor	A hand-held pneumatic device designed to provide external vibrations to the chest wall of a patient to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
80	Pressure algometer/aesthesiometer	An instrument designed to measure a patient's sensitivity to pain (pain threshold) and tactile sensibility.	B
81	Pulmonary resuscitator	A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration.	C
82	Pulse Co-oximeter	A device designed to detect hypoxia via the transcutaneous multiwave measurement and display of carboxy-haemoglobin saturation (SpCO) and typically other related parameters such as haemoglobin oxygen saturation (SpO2), methaemoglobin saturation (SpMet), and haemoglobin concentration (SpHb).	B

83	Pulse oximeter	A device intended for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2).	C
84	Rebreathing oxygen face mask	A flexible, form-shaped device designed to be placed over the nose and mouth to deliver a proportional mixture of air/oxygen (O2) to a patient's airway.	A
85	Respiration monitor	A device designed to measure and display a non-ambulatory patient's respiratory functions. Measurements include concentration of respiratory gas components and/or continuous monitoring of the inspiration/expiration cycle including respiration rate, air volume, and cessation of breathing (apnoea).	B
86	Respiratory oxygen monitor	An instrument designed to continuously measure the concentration of oxygen (O2) inspired by a patient in a respiratory maintenance/therapy setting.	B
87	Respiratory oxygen therapy monitor/regulator	An electrically-powered unit designed to be connected to a pulse oximeter sensor and used during the administration of oxygen (O2) to a spontaneously breathing patient, for: 1) continuous monitoring of physiologic parameters, especially haemoglobin oxygen saturation (SpO2); and 2) dynamic regulation of the amount of O2 delivered to the patient based on physiological parameter measurements.	B
88	Rigid non-bladed video intubation laryngoscope	A non-sterile device intended to facilitate the positioning of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.	A
89	Saddle block anaesthesia kit	A collection of devices designed to deliver an analgesic or anaesthetic agent to the lower dural sac in the region corresponding to the buttocks, in the perineum, or to the inner aspects of the thighs.	B
90	Spinal needle bioimpedance navigation unit	A device designed to transmit and receive electrical signals to/from a dedicated spinal needle and to analyse bioimpedance data in real-time, to predict needle tip location.	D
91	Spirometer/pulmonary function analyser syringe	A device consisting of a barrel (cylinder) with plunger/piston intended to be used for injecting small volumes of accurately measured amounts of gas into a spirometer, pulmonary function analyser, or other diagnostic pulmonary measuring/testing device for calibration or reference.	A
92	Tracheal surgery dilator	A hand-held manual surgical instrument intended to be used during surgical intervention of the trachea to dilate tracheal structures/passages, typically during the creation of a tracheostoma and/or for expanding the margins of a tracheostoma to assist in the insertion of a tracheostomy tube.	A
93	Tracheotome	A surgical instrument designed to cut an opening into the trachea (windpipe) through the anterior surface of the neck to create an artificial airway (tracheotomy).	A

94	Ultrasonic cough stimulation system	An assembly of devices designed to stimulate a reflex cough using ultrasound in a patient who cannot cough on command, typically respiratory patients with cortical insufficiency or the very young/elderly, to help clear the lungs of secretions and aspirated materials.	A
95	Ultrasonic respiratory humidifier	A device designed to agitate water into micro-particles with ultrasound to add moisture to the flow of air/gases administered to a patient via a breathing tube/circuit.	B
96	Vacuum-assisted airway secretion-clearing system	A device assembly designed to remove excessive secretion from the lungs and upper airway of patients with respiratory disease or during cardiac rehabilitation through vacuum technology.	B
97	Venturi oxygen face mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver a mixture of an almost precise ratio of air and oxygen to the patient's airway. The device usually has a replaceable part (Venturi tube) to change the mixture ratio of air and oxygen so that oxygen is delivered at a desired concentration. The device is connected to the oxygen source via a tube. The device has a head strap for fixation. Normally comes with an adapter to connect with humidifier.	B
98	Venturi oxygen face mask	A device designed to be placed over the nose and mouth of a patient to deliver a near-precise mixture of air and oxygen (O2) to a patient's airway without the use of a gas mixer.	B
99	Bronchial cannula	A tube-shaped surgical instrument that is inserted into the lumen of the bronchus by means of a trocar blade to provide rigidity.	A
100	Bronchoscopy tube	A device which is inserted orally into the trachea to maintain airway patency and/or to deliver anaesthetic inhalation agents or other medical gases, and secure ventilation during diagnostic or therapeutic bronchoscopy using a flexible bronchoscope.	C
101	Bulk oxygen concentration system	An assembly of devices designed to concentrate oxygen (O2) from ambient air and then deliver the concentrated O2, with purity of up to 99.5%, to the hospital medical gas supply system.	B
102	Endotracheal secretion monitoring system	An assembly of devices designed to continuously detect the sound of endotracheal (ET) secretions moving through a ventilation circuit during suctioning of an artificially ventilated and/or spontaneously breathing patient to assess the effectiveness of suctioning.	B
103	Epidural anaesthesia kit	A collection of devices intended to be used to deliver an analgesic or anaesthetic agent to the epidural space for pain management.	C

104	Laryngeal airway	A curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients.	A
105	Medicine chamber spacer	A device intended to be placed between a nebulizer or a metered dose inhaler (MDI) and the patient's mouth, to function as a reservoir into which an aerosol medication is dispensed in order to minimize delivery of large aerosolized particles.	A
106	Nasopharyngeal airway	A rubber or plastic tube that extends into the pharynx from either naris to maintain airway patency.	B
107	Oropharyngeal airway	A curved metal or plastic tube inserted through the mouth to facilitate airway patency for gas exchange or suctioning. The device prevents the tongue from obstructing airflow.	A
108	Oxygen/air/nitrous oxide breathing gas mixer	An device designed for accurate mixing of oxygen (O2) and air or O2 and nitrous oxide (N2O) in pre-set concentrations appropriated for breathing.	C
109	Peak flow meter	A device designed to measure the maximum rate of expiratory gas flow [peak expiratory flow (PEF) or peak expiratory flow rate (PEFR)] and forced expiratory volume (FEV) from the lungs. The device is typically intended to monitor the respiratory status of a patient suffering from chronic respiratory disease in a clinical setting or the home.	B
110	Pulmonary function analysis system	A device used to measure the function of the respiratory system in adults and compliant children.	B
111	Retrograde endotracheal intubation kit	A collection of devices used to assist in the placement of an endotracheal (ET) tube during difficult/emergency airway access procedures	B
112	Tracheostomy kit	A collection of surgical instruments, dilators, tracheostomy tubes and other items intended to be used to create a percutaneous opening in the trachea (tracheotomy) for the insertion of a tracheostomy tube to relieve upper airway obstruction and to facilitate ventilation.	C

Note:Accessories/components of medical devices imported as a system need not be registered separately. However this does not debar from risk based classification of Accessories/components of medical devices.

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (146) **Date:** 26 JUL 2021

Subject: Classification of Medical Device pertaining to Interventional Radiology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc./03/2020-DC (146)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

Notice

Classification of Medical Devices Pertaining to Interventional Radiology

S.No.	Medical Device Name	Intended Use	Risk Class
1	Scintillation (gamma) camera	A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector.	A
2	Positron camera	A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body.	A
3	Nuclear whole body counter	A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body.	A
4	Bone densitometer	A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues.	C
5	Bone sonometer	A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk.	B
6	Emission computed tomography system.	An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data	C
7	Fluorescent scanner	A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays.	C
8	Nuclear rectilinear scanner	A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient.	A
9	Nuclear tomography system	A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes.	C
10	Nuclear uptake probe	A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region	A
11	Nuclear whole body scanner	A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide-aperture detector whose position moves in one direction with respect to the patient.	A
12	Nuclear scanning bed	A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure.	A
13	Radionuclide dose calibrator	A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients	B
14	Radionuclide rebreathing system	A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere).	C
15	Nuclear sealed calibration source	A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.	A
16	Nuclear electrocardiograph synchronizer	A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images	A

17	Nonfetal ultrasonic monitor	A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion	B
18	Ultrasonic pulsed doppler imaging system	An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion.	B
19	Ultrasonic pulsed echo imaging system	An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.	B
20	Diagnostic ultrasonic transducer	A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices.	B
21	Angiographic x-ray system	An angiographic x-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium.	C
22	Diagnostic x-ray beam-limiting device	A diagnostic x-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic x-ray field by limiting the size of the primary x-ray beam	C
23	Cine or spot fluorographic x-ray camera	A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an image intensifier	C
24	Electrostatic x-ray imaging system	An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x-radiation into an electrostatic image and, subsequently, into a visible image.	C
25	Radiographic film marking system	A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.	A
26	Image-intensified fluoroscopic x-ray system	An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification.	C
27	Non-image-intensified fluoroscopic x-ray system	A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of x-radiation into a visible image.	C
28	Spot-film device	A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy	B
29	Diagnostic x-ray high voltage generator	A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes.	A
30	Mammographic x-ray system	A mammographic x-ray system is a device intended to be used to produce radiographs of the breast	C

31	Photofluorographic x-ray system	A photofluorographic x-ray system is a device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body	C
32	Diagnostic x-ray tube housing assembly.	A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes.	A
33	Diagnostic x-ray tube mount	A diagnostic x-ray tube mount is a device intended to support and to position the diagnostic x-ray tube housing assembly for a medical radiographic procedure.	A
34	Pneumoencephalographic chair	A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).	B
35	Radiologic patient cradle	A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.	A
36	Radiographic film	Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.	A
37	Radiographic film cassette	A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film	B
38	Radiographic film/cassette changer	A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.	B
39	Radiographic film/cassette changer programmer	A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.	B
40	Wall-mounted radiographic cassette holder	A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use	A
41	Radiographic film illuminator	A radiographic film illuminator is a device containing a visible light source covered with a translucent front that is intended to be used to view medical radiographs	A
42	Automatic radiographic film processor	An automatic radiographic film processor is a device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes.	C
43	Radiographic grid	A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor	A
44	Radiographic head holder	A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.	A
45	Radiologic quality assurance instrument	A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device.	A
46	Radiographic intensifying screen	A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident x-ray photons into visible light and intended for medical purposes to expose radiographic film.	A
47	Radiographic ECG/respirator synchronizer	A radiographic ECG/respirator synchronizer is a device intended to be used to coordinate an x-ray film exposure with the signal from an electrocardiograph (ECG) or respirator at a predetermined phase of the cardiac or respiratory cycle.	A

48	Radiologic table	A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.	A
49	Transilluminator for breast evaluation	A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700-1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.	D
50	Medical image storage device	A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.	A
51	Radiological computer-assisted diagnostic software for lesions suspicious of cancer	A radiological computer-assisted diagnostic software for lesions suspicious of cancer is an image processing prescription device intended to aid in the characterization of lesions as suspicious for cancer identified on acquired medical images such as magnetic resonance, mammography, radiography, or computed tomography. The device characterizes lesions based on features or information extracted from the images and provides information about the lesion(s) to the user.	C
52	Medical image analyzer	Medical image analyzers, including computer-assisted/aided detection (CADe) devices for mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection, is a prescription device that is intended to identify, mark, highlight, or in any other manner direct the clinicians' attention to portions of a radiology image that may reveal abnormalities during interpretation of patient radiology images by the clinicians. This device incorporates pattern recognition and data analysis capabilities and operates on previously acquired medical images. This device is not intended to replace the review by a qualified radiologist, and is not intended to be used for triage, or to recommend diagnosis.	B
53	Radiological computer aided triage and notification software	Radiological computer aided triage and notification software is an image processing prescription device intended to aid in prioritization and triage of radiological medical images. The device notifies a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis of those images performed by the device.	C
54	Full-body MRI system, permanent magnet	A general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body. It includes a permanent magnet assembly.	C
55	Full-body MRI system, resistive magnet	A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). It includes a resistive magnet assembly.	C
56	Full-body MRI system, superconductin g magnet	A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). This system includes a superconducting magnet assembly.	C

57	Foetal cardiac monitor	A mains electricity (AC-powered) device designed to detect, measure, and display foetal heart activity during the perinatal period.	C
58	Foetal Doppler system	A portable, hand-held, battery-powered device assembly consisting of a measuring and display unit and an attached probe or interchangeable probes designed to noninvasively detect foetal heart beats using ultrasound/Doppler technology. The heart beats are typically conveyed audibly via the measuring/display unit and attached probe which is applied to the surface of the pregnant woman's abdomen. The device aids in determining foetal viability.	C
59	Flexible ultrasound colonoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract]. It is inserted through the anus during colonoscopy.	B
60	Flexible ultrasound duodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the duodenum (the first part of the small intestine). It is inserted into the body through the mouth during duodenoscopy.	B
61	Flexible ultrasound gastroduodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct]. It is inserted into the body through the mouth during gastroduodenoscopy.	B
62	Flexible ultrasound laparoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs. It is inserted through an incision made in the abdominal wall (routinely just below the umbilicus) during laparoscopy.	B
63	Flexible ultrasound bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy.	B
64	Bladder ultrasound imaging transducer	An ultrasound imaging transducer assembly specifically designed to be positioned within the bladder either manually or under endoscopic guidance that steers, focuses, and detects the ultrasound beam and resulting echoes either mechanically or electronically.	B
65	Blood flowmeter catheter, Doppler	A flexible tube intended to be inserted into the lumen of a blood vessel to determine blood-flow velocity by measuring the ultrasonic frequency shift between transmitted and reflected signals (Doppler principle).	C
66	General-purpose ultrasound imaging system	A stationary or mobile (e.g., on wheels) assembly of devices designed to collect, display, and analyse ultrasound images during a variety of extracorporeal and/or intracorporeal (endosonography or endoscopic) ultrasound imaging procedures (e.g., cardiac, OB/GYN, endoscopy, breast, prostate, vascular, and intra-surgical imaging).	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (147) **Date:** 26 JUL 2021

Subject: Classification of Medical Device pertaining to Dermatological & Plastic Surgery under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc./03/2020-DC (147)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

Notice

Classification of Medical Devices Pertaining to Dermatological & Plastic Surgery

Sr. No.	Medical Device Name	Intended Use	Risk Class
1	Organ bag.	An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.	B
2	Surgical camera and accessories.	A surgical camera and accessories is a device intended to be used to record operative procedures.	A
3	Implantable ligating clip	An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.	C
4	Laser surgical instrument for use in general and plastic surgery and in dermatology.	A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.	C
5	Low energy ultrasound wound cleaner	A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds.	B
6	Non-powdered surgeon's glove.	A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination	A
7	Surgical drape and drape accessories	A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination.	B
8	Suture retention device	A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient	B

9	Ultraviolet lamp for dermatologic disorders.	An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photo activate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.	B
10	Wound auto fluorescence imaging device	A wound auto fluorescence imaging device is a tool to view auto fluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.	B
11	Battery-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a battery-driven device	B
12	Carbon dioxide laser	A gas laser that is used in surgical procedures. It utilizes carbon dioxide as the substrate. It is widely used in several clinical fields (e.g., gynecology, neuroscience, dermatology).	C
13	Colonoscope, General & Plastic Surgery	Colonoscopes are used for the removal of foreign bodies, excision of tumors or colorectal polyps (polypectomy), and control of hemorrhage. Routine colonoscopy is important in diagnosing intestinal cancer	B
14	Copper vapour laser	A gas laser used in surgical procedures, etc. It utilizes copper vapor as the substrate. It is used in dermatology, etc. for treatment of cutaneous vascular lesions (e.g., port-wine stains, telangiectasia).	C
15	Cryosurgical unit and accessories	A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.	B
16	Dermal dilator	A device to be temporarily implanted subcutaneously to dilate the surrounding skin. Usually, a balloon is implanted subcutaneously where solutions including saline solution are infused.	B
17	Dermatome	A surgical knife used to harvest the skin for grafting. Either manual or electric-powered.	A

18	Dermatome skin approximation tape	A tape that comes in various sizes with adhesive on both sides. It is attached onto a skin graft knife to collect a skin graft tissue. This device is for single-use.	A
19	Drape adhesive.	A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.	A
20	Electrically-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard soft tissues, or soft tissues.	B
21	Electrosurgical cutting and coagulation device and	Electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.	C
22	Electrosurgical device for over-the- counter aesthetic use	An electrosurgical device for over-the-counter aesthetic use is a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.	B
23	Esophagoscope, General & Plastic Surgery	An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section changes its shape corresponding to the shape of the body cavity. The device is inserted through the oral cavity.	B
24	Eye pad.	An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.	A
25	Gas-powered dermatome	A gas pressure-operated surgical device used to cut a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.	B
26	Gas-powered surgical saw	A saw has a handpiece with an attachment that generates vibration or reciprocal movements. It adopts either a micro or macro design. Rechargeable batteries are used. Usually, compressed air or compressed nitrogen is used.	B

27	Gas-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a gas-driven device.	B
28	Gastroscope, General & Plastic Surgery	A gastroscope is a flexible tube that has a small light and a video camera attached to the end of it. The tube can be used to take tissue samples by inserting instruments such as small pincers.	B
29	General electrosurgical unit	A device accompanied by accessories that cuts/coagulates tissues with a high-frequency current or with the electricity/heat of the heating element. The device is used by a physician to confirm that an incision or coagulation is made as intended, macroscopically or microscopically.	C
30	Hemostatic knife	A surgical severing instrument that is similar to a scalpel, excluding the fact that its blade is designed to be heated with an electric current. The blade transmits heat directly to body tissues to achieve hemostasis. The instrument uses thermal energy for the purpose and requires no grounding pad.	B
31	Hydrophilic wound dressing.	A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon).	A
32	Implantable staple	An implantable staple is a staple-like device intended to connect internal tissues to aid healing.	C
33	Internal tissue marker.	An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.	A
34	Irrigating wound retractor device.	An irrigating wound retractor device is a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound	B

35	Laparoscope, General & Plastic Surgery	"These electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired	B
36	Laparoscopy Tray	Laparoscopy Tray is intended for single-use to enable a suitable trained health care professional to perform an laparoscopic procedure.	A
37	Liposuction catheter	A rigid tube inserted into the subcutaneous layer transdermally for removal of fatty deposits. Aspiration is performed with an appropriate unit. This device is for single-use.	B
38	Manual operating table and accessories and manual operating chair and accessories	A manual operating table and accessories and a manual operating chair and accessories are non-powered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.	A
39	Manually-operated dermatome	A hand-held surgical device used to sever a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.	A
40	Occlusive wound dressing.	An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device.	A
41	Plastic surgery osteotome	A surgical, chisel-like, instrument designed to cut and/or shape small bones and/or cartilage during plastic surgery. It is hand-held by the surgeon who will typically use a surgical mallet or hammer to manually impart an impacting force to the proximal end of the instrument.	A
42	Powered corneal trephine	An electric cylindrical device for ophthalmic surgery equipped with a blade for resection/removal of a ring-shaped piece of corneal tissue (corneal button). For example, when a healthy corneal graft is obtained from a cadaver, the recipient's morbid cornea is resected and removed to allow transplantation of the graft.	B
43	Powered dermatome	An electric surgical device used for removal of the fragment of damaged skin or for thinly slicing the skin of a donor for skin graft. A dedicated blade should be used for these purposes.	B

44	Powered suction pump.	A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter	B
45	Removable skin clip	A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable	B
46	Removable skin staple	A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.	B
47	Reusable dermatome blade	A blade that comes in various sizes, attached to the skin graft knife, and is used to harvest the skin graft. This device is reusable after sterilization. Usually, the blade point should be sharpened periodically.	A
48	Single-use dermatome blade	A blade, available in various sizes, attached to a dermatome for collection of skin grafts. The device is intended for single-use.	B
49	Skin marker	A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.	A
50	Skin Stapler	Skin Stapler is intended to be applied to close lacerations on the outer layer of the dermis.	B
51	Soft tissue trephine	A cylindrical or coronary saw used to resect discs of tissues other than bones. It comes in various sizes and configurations according to the size and hardness of the tissue to be resected.	B
52	Surgical apparel.	Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate	A

53	Surgical guillotine	A cutter that consists of a metal frame. The cutter slides through the frame. It comes in various configurations and sizes according to the type of tissue to be severed. Various cranks or shaft driver mechanisms generate the power.	A
54	Surgical lamp	Identification. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.	A
55	Surgical microscope and accessories.	A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.	A

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (159) **Date:** 26 JUL 2021

Subject: Classification of medical device pertaining to Cardiovascular under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for them with respect to the import, manufacture, , sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

APPENDIX A

File No. 29/Misc./03/2020-DC (159)

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

Classification of Medical Devices Pertaining to Cardiovascular

serial No.	Medical Device Name	Intended Use	Risk Class
1	Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm)	The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.	C
2	Cardiac monitor (including cardiotachometer and rate alarm)	A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.	B
3	Apexcardiograph (vibrocardiograph)	An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.	B

4	Echocardiograph	An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.	B
5	Electrocardiograph	An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by heart.	B
6	Electrocardiograph electrode	An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.	B
7	Vascular clip	A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels other than intracranial vessels.	B
8	Vena cava clip	A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.	B
9	Intra-aortic balloon	An intra-aortic balloon is a prescription device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon.	C
10	Intra-aortic balloon control system (balloon pump)	An intra-aortic balloon control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the	B

		cardiac cycle.	
11	Ventricular bypass (assist) device	A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body.	D
12	Pacing system analyzer	A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester and an external pacemaker pulse generator (EPPG). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.	C
13	Implantable pacemaker pulse generator	An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.	D
14	Pacemaker lead adaptor	A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.	C

15	Pacemaker generator function analyzer	A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.	C
16	Cardiovascular permanent or temporary pacemaker electrode	A temporary pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an external pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.	C
17	Pacemaker test magnet	A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.	A
18	Pacemaker programmers	A pacemaker programmer is a device used to noninvasively change one or more of the electrical operating characteristics of a pacemaker.	C
19	Pacemaker repair or replacement material	A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.	D
20	Annuloplasty ring	An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.	C
21	Carotid sinus nerve stimulator	A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.	D

22	Replacement heart valve	A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.	D
23	Endomyocardial biopsy device	An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart.	D
24	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure	An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (*e.g.,* monitors, detectors, sensors, connectors).	C
25	Cardiopulmonary bypass bubble detector	A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.	B

26	Cardiopulmonary bypass vascular catheter, cannula, or tubing	A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.	B
27	Cardiopulmonary bypass heart-lung machine console	A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.	B
28	Cardiopulmonary bypass defoamer	A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.	C
29	Cardiopulmonary bypass heat exchanger	A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.	B
30	Cardiopulmonary bypass temperature controller	A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.	B
31	Cardiopulmonary bypass arterial line blood filter	A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.	C

32	Cardiopulmonary bypass cardiotomy suction line blood	A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.	B
33	Cardiopulmonary bypass pulsatile flow generator	A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.	D
34	Intraluminal artery stripper	An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriscleroticarteries.)	B
35	External cardiac compressor	An external cardiac compressor is an externally applied prescription device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest. External cardiac compressor devices are used as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (*e.g.,* during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).	C
36	External transcutaneous cardiac pacemaker	An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a	C

		periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.	

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (202)

Date: 26 JUL 2021

Subject: Classification of Medical Device pertaining to Physical support under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix-A

File No. 29/Misc./03/2020-DC (202)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

Notice

Classification of Medical Devices Pertaining to Physical Support

S.No	Name of the Medical Device	Intended use	Classification India as per First Schedule part-1 MDR 2017
1	Ankle continuous passive motion exerciser	Electrical device intended to continuously move the ankle joint (e.g., flexion, inversion/eversion) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joint.	B
2	Ankle/foot orthosis	Intended to encompass the ankle joint, or the ankle and foot, to support, align, prevent, or correct orthopaedic deformities/injuries or to improve function of the ankle and/or foot; it may also be intended to offload and redistribute foot pressures that affect pedal circulation to improve blood flow and help heal diabetic foot ulcers or postsurgical wounds.	A
3	Balance board	Intended to train patient with difficulties in balance (e.g., a paraplegic or a stroke victim) walks for balance training.	A
4	Bed traction frame	Intended to treat patients with fractures and other orthopaedic disorders (e.g., of the lower or cervical spine, hip).	A
5	Body arch traction table	Intended to support the body of a patient and provide traction for the back muscles and spine by flexing the patient into a reverse supine body arch.	A
6	Canalith repositioning procedure chair, manual	Intended to treat balance disorders [e.g., benign paroxysmal positional vertigo (BPPV), canalithiasis] caused by displaced canaliths (otoconia) in the inner ear of the patient	A

7	Cervical spine collar	Intended to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains (often to treat whiplash resulting from an automobile accident).	A
8	Cervical spine immobilization head ring	Intended to be fixed to the skull of a patient at brow level using pointed, steel, threaded bolts (typically four) that are adjusted to penetrate the outer bone of the skull.	D
9	Cervicothoracic spine orthosis	Intended to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine.	A
10	Cervicothoracolumbosacral spine orthosis	Intended to encompass the cervicothoracolumbosacral spine region of the neck and trunk.	A
11	Chest-oscillation airway secretion clearing system	Intended to rapidly inflate and deflate against the chest wall of the patient for promoting airway clearance by creating high frequency chest wall oscillation (HFCWO), resulting in the mobilization of bronchial secretions.	B
12	Collar and cuff arm sling material	Fabric and form composite material intended to immobilize forearm, elbow, humerus or shoulder injuries.	A
13	Cranial orthosis	Intended to be worn on the head of an infant with an abnormal head shape (e.g., due to plagiocephaly, brachycephaly, scaphocephaly), or after craniosynostosis repair surgery, to apply pressure to the cranium and improve cranial symmetry/shape during growth over a period of months.	A
14	Elbow orthosis	Intended to encompass the elbow joint to support, align, prevent, or correct deformities/injuries or to improve function of the elbow.	A
15	Finger orthosis	Intended to encompass the whole or part of the finger to support, align, prevent, or correct deformities/injuries or to improve function of the finger.	A
16	Flotation therapy bed, adult	Intended to minimize pressure points on a patient's body by providing contact with as much of the body surface as possible, typically through a mattress that contains a large volume of constantly moving media, e.g., water, air, or mud that lifts the patient to simulate a floating effect.	B

17	Flotation therapy bed, neonatal	Intended to minimize pressure points on neonatal patient's body by providing contact with as much of the body surface as possible, typically through a mattress that contains a large volume of constantly moving media, e.g., water, air, or mud that lifts the patient to simulate a floating effect.	B
18	Foot orthosis	Intended to encompass the whole or part of the foot, or designed as a plantar insert, and intended to provide rigid or semi-rigid correction of the foot for persons with orthopaedic deformities/injuries of the feet	A
19	Hand orthosis	Intended to encompass the whole or part of the hand to support, align, prevent, or correct deformities/injuries or to improve function of the hand.	A
20	Hand/finger splint	Intended to immobilize an injured hand to protect injuries to, e.g., the digits, metacarpals, and wrist during the healing process.	A
21	Hand/wrist continuous passive motion exerciser	A mains electricity (AC-powered) deviceIntenedd to continuously move the metacarpal/interphalangeal joints (e.g., flexion and extension) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joints.	B
22	Hip/knee continuous passive motion exerciser	A mains electricity (AC-powered) device Intended to provide continuous passive motion (CPM) exercise therapy for the hip and/or knee, typically following joint surgery/trauma to promote healing; some types may also operate with patient assistance under controlled active motion (CAM).	B
23	Horizontal non-powered traction system	Non powered device intended to be attached to a table for the application of constant horizontal traction forces to the cervical or lumbar vertebrae by means of attached harnesses whilst the patient typically lies in a supine position on the table during treatment.	A
24	Incentive spirometer	Intended to be used in respiratory therapy to encourage and motivate deep-breathing manoeuvres, typically for the postsurgical treatment and prevention of atelectasis (lung collapse) and to help facilitate airway opening and clearing.	A

25	Intermittent traction system	It is an AC powered electronic device. Intended to apply and relieve pre-set traction forces from a motor through harnesses typically attached to the cervical or lumbar vertebrae.	B
26	Kinetic bed	Intend to enable continuous change of the patient's lying position, e.g., it can tilt the entire bed mattress support system (this includes the mattress, the framework that supports the mattress, and the bedding) lengthways, sideways or to a near vertical tilt.	A
27	Knee immobilizer	Intended to temporarily render the knee immovable, either preoperatively or following injury or arthroscopy.	A
28	Neuro-controlled ambulation exoskeleton	Intended to assist a patient with a walking disability (neurogenic, muscular, or osseous in origin) regain lost motor function by transmission of the patient's residual nerve function, via cutaneous electrodes, to the device motor assembly.	C
29	Orthopaedic bed	Intended to provide support for skeletal traction to stabilize fracture sites.	A
30	Paediatric dorsiflexion slant board	Intended to be used in the treatment of various medical conditions (e.g., congenital, neurological, post-traumatic) in paediatrics, where tendon tightness and muscle contracture affect the ability to dorsiflex the foot, possibly leading to an abnormal gait	A
31	Parapodium walking frame	Intended to encompasses and provide support for the body of a patient who is unable to stand unassisted to help them move (walk) by changing their centre of gravity (COG).	A
32	Physical therapy massager	Electrically powered device intended to provide therapeutic massage to a larger area than hand-held massaging devices.	B
33	Shoulder continuous passive motion exerciser	It is a mains electricity (AC-powered) device Intended to continuously move the shoulder joint (e.g., flexion, rotation, adduction/abduction) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joint.	B
34	Shoulder immobilizer	Intended to temporarily immobilize or limit abduction of the shoulder joint to support healing of an injury or a surgical wound.	A

35	Swivel-walker	Intended to encompasses and provide support for the body of a patient who is unable to stand unassisted, to help them move (walk) by rocking sideways (shifting their weight from side-to-side with a shoulder movement) which makes the footplate of the device swivel so that it “walks” forward.	A
36	Toe separator	Intended to space the toes of the foot to relieve pain, pressure/friction between toes, and/or to facilitate realignment of the toes to a natural position.	A
37	Traction table, line-powered	Intended to support a patient and to provide traction for the back muscles and spine (e.g., lumbar, cervical) by a motorized mechanical manipulation of the spine.	B
38	Wrist immobilizer	Intended to temporarily render the wrist immovable as therapy for non-displaced fractures, strains, sprains, and muscle injuries of the wrist.	A

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (180)

Date: 06 AUG 2021

Subject: Classification of Medical Device pertaining to Radiotherapy under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

APPENDIX A

File No. 29/Misc./03/2020-DC (180)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

Classification of Medical Devices Pertaining to Radiotherapy

Sr. No.	MEDICAL DEVICE NAME	INTENDED USE	RISK CLASS
1	Medical charged-particle radiation therapy system	A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy.	C
2	Absorbable perirectal spacer	An absorbable perirectal spacer is composed of biodegradable material that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum.	C
3	Absorbable tissue spacer for radiotherapy	An absorbable material used to reduce radiation exposure of normal tissue during radiotherapy by implanting surgically or percutaneously between tissue, internal organs, etc. , to make a space between the malignant tumor and normal tissue.	D
4	Applicator for bile duct manual brachytherapy	A manual brachytherapy applicator specifically designed for bile duct radiation therapy. An applicator designed to have a configuration that facilitates manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bile duct.	C
5	Applicator for bladder manual brachytherapy	A manual brachytherapy applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bladder.	C

6	Applicator for bladder remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bladder radiation therapy. It is designed to be temporarily implanted in the bladder. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	C
7	Applicator for brachytherapy bile duct remote after loading	A remote controlled brachytherapy applicator specifically designed for bile duct radiation therapy. It is designed to be temporarily implanted in the bile duct. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	C
8	Applicator for brachytherapy Cervical/endometrial remote after loading	A remote controlled brachytherapy applicator specifically designed for uterine cervical or intrauterine radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the uterine cervix and endometrium.	C
9	Applicator for brachytherapy non-central circulatory general-purpose manual	A general-purpose brachytherapy applicator used to facilitate radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy, and placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the non-central circulatory system.	C
10	Applicator for brachytherapy non-central circulatory general-purpose remote after loading	A general-purpose remote controlled brachytherapy applicator used to facilitate radiotherapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the non-central circulatory system.	C

11	Applicator for bronchial manual brachytherapy applicator	A manual brachytherapy applicator specifically designed for temporarily use in bronchial radiation therapy. A single or module applicator designed to facilitate manual placement (placement using an endoscope or positioning, placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources.	C
12	Applicator for bronchial remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bronchial radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the bronchus. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	C
13	Applicator for esophagus manual brachytherapy	A manual brachytherapy applicator specifically designed for esophagus radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the esophagus. It may be designed to be standard in configuration or to handle specific radiation sources.	C
14	Applicator for esophagus remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for esophagus radiation therapy. It is designed to be temporarily implanted in the esophagus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	C
15	Applicator for eye manual brachytherapy	A template with a groove on the one side. The groove shows the position of the brachytherapy source that is manually, temporarily delivered to the eye surface. The other side is shielded.	C
16	Applicator for manual cervical/endometrial brachytherapy	A manual brachytherapy applicator specifically designed for uterine cervix or intrauterine radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, placement with an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites.	C

17	Applicator for manual rectal/anal brachytherapy	A manual brachytherapy applicator specifically designed for rectal and/or anal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the rectum and/or anus.	C
18	Applicator for nasopharynx manual brachytherapy	A manual brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the nasopharynx.	C
19	Applicator for nasopharynx remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the nasopharynx.	C
20	Applicator for neck manual brachytherapy	A manual brachytherapy applicator specifically designed for neck radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the neck tissues.	C
21	Applicator for neck remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for neck radiation therapy. It is designed to be temporarily implanted in the neck tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	C
22	Applicator for pancreas manual brachytherapy	A manual brachytherapy applicator specifically designed for pancreatic radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement, or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the pancreas. It may be designed to be standard in configuration or to handle specific radiation sources.	C
23	Applicator for pancreas remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for pancreatic radiation therapy. It is designed to be temporarily implanted in the pancreas. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	C

24	Applicator for prostate manual brachytherapy	A manual brachytherapy applicator specifically designed for prostate radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement or removal with a trigger loading device, an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the prostate gland. It may be designed to be standard in configuration or to handle specific radiation sources.	C
25	Applicator for prostate remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for prostate radiation therapy. It is designed to be temporarily implanted in the prostate gland. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	C
26	Applicator for rectal/anal remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for rectal or anal radiation therapy. It is designed to be temporarily implanted in the rectum or anus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	C
27	Applicator for tongue manual brachytherapy	A manual brachytherapy applicator specifically designed for lingual radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the tongue and the surrounding tissues. It may be designed to be standard in configuration or to handle specific radiation sources.	C
28	Applicator for tongue remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for tongue or oral cavity radiation therapy. It is designed to be temporarily implanted in the tongue or the surrounding tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	C
29	Applicator for vaginal manual brachytherapy	A manual brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites.	C
30	Applicator for vaginal remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the vagina.	C

31	Bile duct brachytherapy system applicator, remote-after loading	A remote after loading brachytherapy applicator specifically designed for use in radiation therapy treatments of the bile duct. It is designed for temporary insertion into the bile duct and serve as a guide for computer-controlled placement and removal of single or multiple radioactive sources.	C
32	Bladder brachytherapy system applicator, manual	A manual brachytherapy applicator specifically designed to be used in radiation therapy treatments of the bladder.	C
33	Blood vessel manual brachytherapy applicator	A manual brachytherapy applicator designed exclusively for blood vessel radiotherapy. Most commonly, it is used to prevent formation of plaque, stenosis and restenosis in blood vessels after surgery. A single or module device designed to facilitate manual placement (placement and removal under endoscopy or using an image diagnostic system) of single or multiple therapeutic radiation sources in the treatment site.	D
34	Blood vessel remote after loading brachytherapy applicator	A remote controlled brachytherapy applicator designed exclusively for radiotherapy in blood vessels. This treatment is used to prevent plaque formation. and stenosis in blood vessels after surgery. It is designed for temporary implantation in a blood vessel, and serves as a guide for computer-controlled temporary placement and removal of single or multiple therapeutic radiation sources at treatment sites.	D
35	Brachytherapy needle	A sterile, sharp bevel-edged, hollow tubular metal instrument that is used to inject radionuclide into a body cavity or tissue as a source of nuclear radiation for cancer therapy (brachytherapy).	B
36	Brachytherapy radionuclide phantom, anthropomorphic	A device that consists of preserved human or animal tissue, or a two or three-dimensional (3-D) tissue-equivalent model designed to simulate the functional, physical, or a combination of these characteristics of normal or diseased human organs.	B
37	Brachytherapy system chair	A mains electricity (AC-powered) device (a chair or stool) that is a component of a brachytherapy system and which is specifically designed to support and position a patient during brachytherapy radiation treatments given by either a manual applicator or a remote after loading brachytherapy system applicator.	B
38	Brachytherapy system remote after loading source safe	A component of a remote after loading brachytherapy system consisting of a shielded vault, and associated source retraction and extrusion mechanisms, alarms, and related mechanical, electronic and software controls, used to shield the brachytherapy sources in order to protect system operators, brachytherapy patients and others from the continuous emissions of the radioactive brachytherapy source(s) when they are not in use.	C

39	Brachytherapy system remote after loading source transfer tube	The transfer tube, when attached to the applicator and the after loading system, provides a continuous closed passage that allows for moving either a radioactive source(s) and/or positioning markers from the shielded source storage compartment of the remote after loading brachytherapy system into appropriate positions within a brachytherapy applicator that has been positioned at a location either on the surface of, or within, the patient.	C
40	Brain brachytherapy system applicator, remote-after loading	A remote after loading brachytherapy applicator specifically designed for use in radiation therapy treatments of the brain. It is designed for temporary implantation within the body and serve as a guide for computer-controlled placement and removal of single or multiple radioactive sources in the brain.	C
41	Brain manual brachytherapy applicator	An applicator specifically designed for brain radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, placement under endoscopy, or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in the brain.	D
42	Brain remote after loading brachytherapy applicator	A remote controlled brachytherapy applicator designed exclusively for brain radiotherapy for temporary implantation in the body. It serves as a computer-controlled guide for temporary placement and removal of a single or multiple therapeutic radiation sources in the brain.	D
43	Breast ductography cannula	A thin, sterile, semi-rigid or rigid metal tube that is inserted into the nipple of the female breast to inject a contrast medium into the lactiferous ducts to enhance their visualization during a radiographic procedure.	C
44	Central circulatory general-purpose manual brachytherapy applicator	A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the central circulatory system.	D
45	Central circulatory general-purpose remote after loading brachytherapy applicator	Intended to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the central circulatory system.	D
46	Central circulatory manual brachytherapy therapeutic radionuclide system	A device that places a radiation source manually or automatically at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device does not equip a remotely controlled radiation source transporter.	D

47	Central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system to be placed permanently in the body for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. The radiation source, which is permanently placed manually, is designed to achieve compatibility with tissues. The radiation source can be selected from the following forms – e.g., microsphere, globe, stent, seed, and wire- in order to generate low-energy photons, beta particles, or alpha particles.	D
48	Central circulatory remote after loading brachytherapy therapeutic radionuclide source	A device for the central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor.	D
49	Central circulatory remote after loading brachytherapy therapeutic radionuclide system	A device that places a radiation source temporarily at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.	D
50	Central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system that uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor, and is placed in the body temporarily, and removed after the pre-determined treatment period. The radiation source, which is temporarily inserted manually, is supplied in various forms – e.g., encapsulated, sealed, plated, foiled, or embedded.	D
51	Compact thermoluminescent dosimetry electrometer	Thermoluminescence dosimeter (TLD) is used to measure the radiation dose emitted to the phantom, eyes and other organs with high radio sensitivity.	A
52	Conformal Brachytherapy Source	The intended use of the device is for the treatment of cancer by temporary intraoperative or surface irradiation. The device contains radioactive material with activity up to 200 mci and is indicated for treatment of temporary intraoperative, interstitial, intracavitary or surface application to treat selected localized tumors.	C
53	High-frequency hyperthermia system	A system used to generate high-temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases.	C
54	Intra-vaginal organ positioning device for diagnostic imaging and radiotherapy	A device that is specifically designed to be inserted in the vagina to properly position and fix the surrounding organs such as uterine cervix, rectum, and urinary bladder for image diagnosis or radiotherapy. This device is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	B

55	Laser irradiation therapy kit	A kit includes a puncture needle, a guide wire, and a guiding sheath for guiding probes (used for laser irradiation therapy, for example). Not all of the components are included; in some products, two or more of components are integrated into one.	B
56	Light beam patient position indicator	A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam.	A
57	Living tissue radiotherapy system	A low energy X-ray therapy system designed to treat adjacent tumor lesions with high dose X-rays by placing soft X-ray beams from 5 to 50 kV inside the tumor tissue. It is used in both intraoperative radiation and stereotactic localized radiation therapy.	C
58	Manual radionuclide applicator system	A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy.	A
59	Medical neutron radiation therapy system	A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy	C
60	MOSFET radiation therapy dosimetry system	An assembly of devices using metal oxide semiconductor field-effect transistor (MOSFET) technology intended to be used for on-the-spot patient or anthropomorphic radiation dose verification and monitoring during radiation therapy and radiology procedures. Applications typically include radiation oncology therapy and dosimetry, treatment plan verification for in vivo dosimetry, brachytherapy, intraoperative radiation therapy, image-guided radiation therapy, and research.	B
61	Non-central circulatory manual brachytherapy therapeutic radionuclide system	A device that places a radiation source manually or automatically at the treatment site in the non-central circulatory system for providing a required radiation dose during radiotherapy.	C
62	Non-central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device which is histocompactible and containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be permanently implanted in the body for radiation therapy requiring treatment or symptomatic treatment.	C
63	Non-central circulatory remote after loading brachytherapy therapeutic radionuclide source	A device for the non-central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor.	C

64	Non-central circulatory remote after loading brachytherapy therapeutic radionuclide system	A device that places a radiation source temporarily at the treatment site in the non-central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.	C
65	Non-central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be temporarily implanted in the body and to be removed after a prescribed duration of treatment. Used in brachytherapy, the device is placed and removed manually or under endoscopic observation.	C
66	Non-powered accelerator system table	A mechanically-operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses a medical linear accelerator or non-linear accelerator.	A
67	Non-powered neutron therapy table	A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from a nuclear reactor, etc. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical table top positioning control and table height control.	A
68	Radionuclide brachytherapy table	A programmable bed for electric radiotherapy to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically.	B
69	Non-powered remote irradiation therapy table	A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote radionuclide radiotherapy apparatus.	A
70	Non-powered X-rays radiation therapy table	A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus.	A
71	Operator radiation protection spectacles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment.	B
72	Patient positioning device for breast diagnostic imaging and radiotherapy	A device that is specifically designed to properly position and fix a female patient's breasts and chest for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	B
73	Patient positioning device for extremity diagnostic imaging and radiotherapy	A device that is specifically designed to properly position and fix a patient's arms and legs for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	B
74	Patient positioning device for pelvis diagnostic imaging and radiotherapy	The device that consists of frames, plates, or other parts, and is specifically designed to properly position and fix the patient's abdomen and pelvic region for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	B

75	Patient positioning device for whole body diagnostic imaging and radiotherapy	A device that consists of fixed or adjustable parts (e.g., frames and plates), and is specifically designed to properly position and fix the patient's whole body for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	B
76	Post Breast Biopsy Hemostatic Breast Compression Device	Intended to achieve and maintain hemostasis of a breast biopsy wound site.	C
77	Powered neutron therapy table	A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from the nuclear reactor, etc.	B
78	Powered patient table for accelerator	A bed operates by programmable for electric radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses medical linear accelerator or non-linear accelerator.	B
79	Powered radiation therapy patient support assembly	A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy	C
80	Powered radionuclide brachytherapy table	A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically.	B
81	Powered remote irradiation therapy table	A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote cobalt 60 radiotherapy apparatus and other remote radionuclide radiotherapy apparatuses.	B
82	Powered X-rays radiation therapy table	A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus.	B
83	Radiation therapy beam-shaping block	A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source	C
84	Radiation therapy simulation system	A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced.	C
85	Radiographic Protective Glove	A personnel protective glove is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation	B

86	Radionuclide brachytherapy source	A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy	C
87	Radionuclide dynamic function testing equipment	A device used to measure and record temporal variations of radioisotope concentrations in the body. Specialized devices, such as devices for thyroid uptake measurement, renograms, and radioisotope blood volume measurement, are included.	B
88	Radionuclide radiation therapy system.	A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body.	C
89	Radionuclide source for remote irradiation therapy	Radiation sources generated in a reactor and used as in a remote after loading system designed to deliver a therapeutic radiation beam to a target anatomical area. The radiation sources incorporated as a component of the remote after loading system are generally sealed.	C
90	Radionuclide system contour detector for remote irradiation therapy	Intended to precisely determine the outline of the area of the body to be irradiated. Usually, the information obtained from this device is entered into a radiotherapy planning system and utilized for the radiotherapy plan.	C
91	Real-time position management respiratory gating system, optical	An assembly of electronic devices designed to track the respiratory pattern of a patient by means of optical technology to correlate tumour position with the respiratory cycle during radiation treatment planning, radiotherapy, computed tomography (CT) imaging, or other radiation procedures.	C
92	Rectal balloon for prostate immobilization	A rectal balloon for prostate immobilization is a single use, inflatable, non-powered positioning device placed in the rectum to immobilize the prostate in patients undergoing radiation therapy.	C
93	Remote controlled radionuclide applicator system	A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy.	C
94	Stationary radiation protection barrier	A device for permanent installation that forms a structural barrier that shields or attenuates radiation emitted from primary radiation source or scattered radiation source.	B
95	Stereotactic radiotherapy accelerator system	A stereotactic radiation therapy system for treatment based on a linear accelerator (or microtron). The device may be used to inactivate lymphocytes.	C
96	X-ray CT system for radiotherapy planning	A X-ray CT system that has a special configuration, containing hardware, software, etc. used in radiotherapy planning. It is used to determine the size and positioning of the therapeutic radiation field based on a series of treatment parameters to be generated.	C

97	X-ray radiation therapy system	An x-ray radiation therapy system is a device intended to produce and control x-rays used for radiation therapy.	C
98	X-ray/CT combined linear accelerator system	A combined system of a linear accelerator system and an X-ray CT system for radiotherapy planning.	C
99	X-ray/CT combined particle radiotherapy equipment	A combined system of particle radiotherapy equipment and an X-ray CT system for radiotherapy planning.	C
100	Patient Positioning System, Ultrasound	An assembly of devices used to locate, with ultrasound, internal soft-tissue anatomy that moves relative to external or bony landmarks, to enable subsequent adjustment of the patient for precise external beam radiation treatment of the target tissue. It typically includes an ultrasound imaging system, computerized workstation(s), optical tracking devices, and dedicated software.	C
101	X-ray/MR combined linear accelerator system.	A system intended to provide treatment planning, image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment in indicated. The system operates on the principle of linear acceleration of electrons, providing a predictable radiation field in a beam of well-defined dimensions	C

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (197) **Date: 06 AUG 2021**

Subject: Classification of Medical Device pertaining to Respiratory under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC(197)

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Classification of Medical Devices Pertaining to Respiratory

Sr. No.	Medical Device Name	Intended use	Risk Class
1	Activated-oxygen generator	It is a device that makes activated oxygen (singlet oxygen) which is mixed with room air and produces activated water as a by-product.	B
2	Argon gas analyser	An instrument intended to measure the concentration (partial pressure) of argon (Ar) in a gas mixture sample to aid in determining a patient's ventilatory status.	B
3	Artificial airway tube cuff pressure monitor	A device intended to intermittently or continuously measure the internal pressure in the cuff of an endotracheal (ET)/endobronchial/tracheostomy tube when this has been situated into the tracheal passage.	B
4	Bulk oxygen concentration system	An assembly of devices designed to concentrate medical grade oxygen (O2) from ambient air and then deliver the concentrated O2, with purity of up to 93%-99.5%, to the hospital medical gas supply system for therapeutic use on patients in Hospital.	A
5	Cardiopulmonary resuscitation mask	A device that intended to be placed over a patient's mouth to administer "mouth-to-mask" exhaled air from the user to the patient during cardiopulmonary resuscitation (CPR).	A
6	Cerebral oximeter	A device used as an adjunct monitor for the regional haemoglobin oxygen saturation of blood in the brain of a patient.	B
7	Chest-oscillation airway secretion-clearing system	Devices designed to provide high frequency chest wall oscillation (HFCWO) for external chest wall manipulation intended to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
8	Chest-percussion airway secretion-clearing system	Devices designed to provide external mechanical percussion (rapid tapping) to the chest wall of a patient to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
9	Cold-air diagnostic inhalation system	An assembly of devices intended to be used in the assessment of a pateint suffering from asthma.	B

10	Cough long-term ambulatory recording system	An assembly of devices intended for long-term detection and recording of the number of times a patient coughs during daily activities or sleep.	A
11	Cricothyrotome	A hand-held manual surgical instrument intended to be used to perform a cricothyrotomy providing airway access within seconds for immediate ventilation of the patient and necessary suction procedures.	B
12	Dry powder inhaler	A hand-held device designed to administer powdered medicine through the mouth and into the bronchial airways.	A
13	Dry salt therapy device	A hand-held inhaler prefilled with salt crystals and used to provide an inhalation of salt particles through the mouth and into the bronchial airways to induce natural self-cleansing mechanisms that flush away the impurities from the surface of cells and mechanically clean the airways.	A
14	Electroacoustical airway secretion-clearing system	An assembly of devices designed to provide externally applied vibrations to the chest wall of a patient via an electroacoustical transducer (the applicator) to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
15	Endotracheal tube introducer	A device designed to help with the insertion of an endotracheal (ET) tube into the airways of a patient during intubation	A
16	Exhaled-gas oesophageal intubation detector	A device designed to verify proper endotracheal (ET) tube placement by detecting/assessing escaping levels of exhaled carbon dioxide (CO2) during airway management disclosing potential incorrect intubation.	A
17	Foetal pulse oximeter	A photoelectric device designed for the monitoring of intrapartum foetal oxygen saturation (FSpO2) in the presence of a non-reassuring foetal heart rate (FHR) pattern during labour.	B
18	Gas pipeline/supply system air compressor	A device designed to create compressed medical grade air, and supply it to a hospital or institution's gas pipeline/supply system for patient use.	B
19	Heated respiratory humidifier	A device designed to heat and humidify air/oxygen inspired by a patient to help maintain the mucous membranes of the respiratory tract typically during periods of prolonged respiratory support/therapy.	B
20	Home-use sleep apnoea recording system	A device intended to continuously measure and record patient physiological parameters during sleep in the home, to facilitate the diagnosis of sleep apnoea.	B

21	Hyperbaric chamber	The intended use of the Hyperbaric Chamber is to administer 100% oxygen at pressure greater than ambient.	C
22	Hypopnea sensor/alarm	An electronic device intended to be used to indicate patient hypopnea by monitoring the movement of the thorax and abdomen with each breath and provides a signal, according to predetermined settings.	B
23	Impedance pneumography recording/analysis system	An assembly of electronic devices intended for continuous recording of a patient's pulmonary function parameters using impedance pneumography (IP).	B
24	Implantable sleep apnoea treatment system	An assembly of devices intended for home management of obstructive sleep apnoea (OSA) using an implanted stimulator to provide electrical stimulation to the hypoglossal nerve.	C
25	Infant apnoea monitor	A device that is used to register the respiratory rate of an infant and which gives an alarm signal (e.g., audible/visual) when the pre-set limits are exceeded caused by an extended interruption or cessation (apnoea) of the infants breathing pattern; a condition known as sudden infant death syndrome (SIDS).	B
26	Manual chest percussor	A hand-held device designed to facilitate manual percussion (rapid tapping) to provide external vibrations to the chest wall of a patient to loosen excessive airway secretions to promote airway clearance and improve bronchial drainage for patients with respiratory disease.	B
27	Nitrogen monoxide analyser	A device intended to measure nitric oxide (NO), in exhaled air to facilitate diagnosis and management of asthma.	B
28	Nitrous oxide analyser	An instrument used to measure the concentration of nitrous oxide (N2O) in a sample of a gas mixture taken from an enclosed environment such as a healthcare facility, a compressed medical air or gas system, and/or devices used for anaesthesia administration or respiratory therapy.	B
29	Pulse oximetry telemetric monitoring system	An assembly of devices designed to continuously measure and wirelessly transmit haemoglobin oxygen saturation (SpO2) signals from a patient to a receiving location for viewing.	B
30	Respiratory apnoea monitoring system	An assembly of devices designed to detect the cessation of breathing (apnoea) in patient who are at risk of respiratory failure to alert a parent or attendant of the life-threatening episode(s).	B

31	Steam inhaler	An electrically-powered, hand-held device designed for the inhalation of steam for the relief of the symptoms (congestion and pressure) associated with upper respiratory disorders.	A
32	Stress test treadmill	A device used as a component of a stress test system that permits the evaluation of a patient's physiologic response to physical stress.	A
33	Therapeutic air ionizer	A device that produces small, biologically-active, negatively-charged ions of oxygen (O2), pulsed at various selected frequencies, that are emitted into the ambient air and absorbed into the bloodstream via the lungs to potentially produce a therapeutic effect.	A
34	Therapeutic positive pressure breathing ventilator	A device used for therapeutic rehabilitation of patients with chronic respiratory diseases, and for the distribution of aerosolized pharmacological agents to the patient's airways and lungs.	C
35	Thoracic bioconductance measurement system	An assembly of devices designed to measure and store bioconductance measurements, analyse the stored data and provide information that can aid a clinician in their evaluation of lesions suspicious of lung cancer.	B
36	Thoracic electrical impedance segmentography system	An assembly of devices designed to perform thoracic bio-impedance measurements to continuously record the distribution of air across 4 quadrants of the lungs, commonly of a neonatal/infant patient to detect changes in lung ventilation at a regional level, to assist in the diagnosis of lung conditions.	B
37	Thoracic electrical impedance tomography system	An assembly of devices designed to perform continuous bio-impedance measurements throughout a cross-section of the thorax, to provide real-time feedback of lung function of a ventilated patient.	C
38	Thoracic suction pump	A device intended to generate negative pressure specifically for aspiration, to remove fluids, secretions and air to allow for the normal expansion/function of the lungs and/or mediastinum.	B
39	Tongue-adjustment sleep apnoea treatment system	An assembly of devices intended for home management of obstructive sleep apnoea (OSA) by monitoring breathing parameters during sleep to detect the onset of an apnoea event and reducing pharyngeal obstruction by the tongue.	B
40	Tracheostoma protective filter	A device designed as a filter for protecting a stomal opening in the windpipe against harmful external influences.	A

41	Tracheostoma protector	A patient-worn device in the form of a patch, collar, or cloth designed to be fastened around the neck to protect a tracheostoma orifice against harmful external influences. It is not intended to be used as a shower shield.	A
42	Tracheostomy tube lubricant	A substance made of oil designed to be applied by healthcare staff or a patient to the outer surface of a tracheostomy tube inner cannula to facilitate its easy sliding into the outer cannula.	A
43	Transcutaneous blood gas monitoring system	An assembly of devices designed for the continuous and transcutaneous measurement of a patient's blood gas parameters detected through the jugular vein (SjvO2).	B
44	Valsalva manoeuvre mouthpiece	A device intended to be inserted into a patient's mouth to facilitate performance of the Valsalva manoeuvre.	A
45	Video intubation laryngoscope handle/monitor	A component of a bladed video intubation laryngoscope intended to enable the positioning of the blade into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.	A
46	Whole-body plethysmograph	A graphic recorder designed for determining and registering airway resistance and thoracic gas volume to assess pulmonary function.	B
47	Diagnostic Spirometer	A device designed to measure several or all respiratory-gas volume and flow parameters needed to evaluate basic pulmonary function.	B
48	Monitoring Spirometer	A device designed to measure continuously a patient's tidal volume or minute volume for the evaluation of the patient's ventilatory status.	B
49	Oxygen Concentrator	A device designed to concentrate oxygen (O2) from ambient air and deliver the concentrated O2 to patient.	B
50	Pulmonary function analysis system	A device used to measure the function of the respiratory system in adults and compliant children.	B
51	Public respirator (2 ply, 3 ply face mask)	A filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates during a public health medical emergency.	A

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Notice

File No. 29/Misc./03/2020-DC (196) **Date: 06 AUG 2021**

Subject: Classification of Medical Device pertaining to ENT under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC(196)

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

Notice

Classification of Medical Devices Pertaining to ENT

Sr. No.	Medical Device Name	Intended Use	Risk Class
1	Adenotome	Surgical instrument intended to dissect the adenoids.	A
2	Adenotome blade	Intended to mount on adenotome and perform dissection of adenoids.	B
3	Audiometer testing system	An assembly of electronic reference devices intended to calibrate an audiometer.	A
4	Audiometer	Intended for evaluation of hearing by generating tones throughout the audible range	B
5	Evoked response auditory stimulator	An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.	B
6	Behind-the-ear air-conduction hearing aid	Intended to compensate for impaired hearing by transmitting amplified sound waves to the eardrum through air.	B
7	Behind-the-ear air-conduction tinnitus masker	Intended to provide noise of sufficient intensity and bandwidth to mask tinnitus.	B
8	Behind-the-ear bone-conduction tinnitus masker	Intended to provide ultrasonic broadband noise and/or sweep-frequency stimuli noise of sufficient intensity and bandwidth to mask tinnitus.	C
9	Cochlear implant assessment system	Intended to perform an integrity test on the implantable portion of a cochlear implant (CI) system in-situ.	C
10	Ear bowl	Constructed to fit the curvature of the head so that it will sit closely under the ear lobe and enable treatments of ear.	A
11	Ear canal impression tray	Intended to hold and confine the impression material in opposition to the surfaces to be recorded, and to control the impression material while it sets to form the impression of the ear canal.	A
12	Ear canal light	Intended to illuminate the ear canal.	A

13	Ear excavator	Designed for cutting, scraping, scooping and removing tissue during a surgical procedure in or around the ear.	A
14	Ear prosthesis	Intended to reconstruct the external ear by replacing damaged or missing tissue.	C
15	Ear wick	Intended to minimize bleeding during ear surgery.	A
16	Electroglottograph	Intended for recording the changes in electrical potential or impedance, resulting from movement of the vocal cords during respiration and phonation.	B
17	Endaural curette	Designed for scraping within the ear canal (e.g., removing wax), and for procedures during middle ear surgery (e.g., removal of the superior bony rim).	A
18	ENT chair, electric	Designed to support a patient in a seated position, electrically control position in a way to facilitate ear, nose, throat examination, treatment, and/or minor surgery.	A
19	ENT chair, mechanical	Designed to support a patient in a seated position, mechanically control position in a way to facilitate ear, nose, throat examination, treatment, and/or minor surgery.	A
20	ENT shaver system	Intended to resect/debride soft and osseous (bone) tissue in the nasal cavity or ear region during ear/nose/throat (ENT) or plastic surgery procedures; including functional endoscopic sinus surgery (FESS).	B
21	ENT surgical microscope	Intended to magnify minute structures (e.g., nerves, vessels) in the performance of ear, nose, and/or throat (ENT) surgery requiring high magnification and adjustable focusing.	A
22	ENT transilluminator	Intended to illuminate sinus tissue during an ear/nose/throat (ENT) procedure to render the tissue translucent for examination	A
23	Evoked-potential audiometer	Electroacoustic instrument designed to evaluate the activity of the auditory pathway of the brain in response to an acoustic signal [auditory brainstem response (ABR)] in patients.	B
24	Flexible fibreoptic nasopharyngo laryngoscope	Flexible endoscope intended for the visual examination and treatment of the nasal passages, including the sinus openings, the pharyngeal end of the auditory tube, the larynx, and the vocal cords.	B
25	Flexible fibreoptic nasopharyngoscope	Flexible endoscope intended for the visual examination and treatment of nasopharynx (the upper part of the throat behind the nose).	B

26	Flexible fibreoptic rhinoscope	Flexible endoscope intended for the visual examination and treatment of nasal cavity.	B
27	Flexible fibreoptic sinoscope	Flexible endoscope intended for the visual examination and treatment of the paranasal sinuses during an ear/nose/throat (ENT) intervention.	B
28	Flexible video antroscope	Flexible endoscope intended for the visual examination and treatment of a cavity, particularly the pathological changes in the area of the maxillary sinus.	B
29	Impedance audiometer	Intended to evaluate the functional condition of the middle ear by changing the air pressure in the external auditory canal to measure and graph the mobility characteristics of the tympanic membrane.	B
30	Nasal septum straightening forceps	Surgical instrument specifically designed to straighten the nasal septum through grasping and manipulation of the bone/cartilage of the septum during nasal reconstructive procedures.	A
31	Otoscope, endoscopic	Intended to be used in otology mainly for observation, diagnosis, and treatment of the outer and/or middle ear.	A
32	Tonsil knife	Intended for the removal of the tonsils during a surgical intervention.	A
33	Tracheal bistoury	Designed for opening abscesses or slitting up sinuses and/or fistulas in the trachea.	A
34	Middle ear mold	A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane.	C
35	Fully-implantable middle ear implant system	An implanted assembly of sterile devices intended to compensate for impaired hearing by transmitting vibrations to the middle ear. It is powered by a battery that is recharged inductively, via an external device.	C
36	Larynx prosthesis	A device used for replacement and restoration of the laryngeal function, or for maintenance of patency of the larynx.	C
37	Epistaxis balloon	Device intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.	B
38	Eustachian tube balloon dilation system	The system is intended for use in dilating the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction.	B
39	Argon laser for otology, rhinology, and laryngology	Device is used for the purpose of coagulating and vaporizing soft and fibrous tissues, including osseous tissue while performing ENT surgical procedure.	C

40	Ear, nose, and throat microsurgical carbon dioxide laser	Device intended for the surgical excision of tissue from the ear, nose, and throat area while performing microsurgical procedures to excise lesions and tumors of the vocal cords and adjacent areas.	C
41	Esophagoscope (flexible or rigid)	Device intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus.	B
42	Mediastinoscope and accessories	Device intended to examine or treat tissue in the area separating the lungs for diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated.	B
43	Laryngostroboscope	A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation.	B
44	Bone particle collector	A bone particle collector is a filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.	A
45	Suction antichoke device	A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.	C
46	Tongs antichoke device	A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient.	C
47	Powered nasal irrigator	A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water.	B
48	External nasal splint	An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.	A
49	Antistammering device	An antistammering device intended to minimize a user's involuntary hesitative or repetitive speech. It also prevent the user from hearing the sounds of his or her own voice	B
50	External upper esophageal sphincter compression device	An external upper esophageal sphincter compression device is intended to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.	C

51	Wireless air-conduction hearing aid	A wireless air-conduction hearing aid is intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.	B
52	Hearing aid calibrator and analysis system	A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer.	B
53	Tympanic membrane contact hearing aid	A tympanic membrane contact hearing aid is a prescription device that compensates for impaired hearing by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.	B
54	Master hearing aid	A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing.	B
55	Active implantable bone conduction hearing system	The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.	C
56	Battery-powered artificial larynx	A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound.	B
57	Nasal dilator	A nasal dilator is a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow.	A
58	Transcutaneous air conduction hearing aid system	A transcutaneous air conduction hearing aid system is a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal.	C
59	Acoustic chamber for audiometric testing	An acoustic chamber for audiometric testing is a room that is intended for use in conducting diagnostic hearing evaluations and that eliminates sound reflections and provides isolation from outside sounds.	A
60	Gustometer	A gustometer is a battery-powered device that consists of two electrodes that are intended to provide galvanic stimulus resulting in taste sensation.	B

61	ENT cupped forceps	A forcep with a spoon-(dish) like configuration at the distal end, and is used to treat the ear, nose, and throat (ENT), and remove tissue from the body.	A
62	Tongue depressor	A surgical instrument used to move the tongue to facilitate examination of surrounding organs and tissue.	A
63	Tonsillectome	A manually operated surgical device used to dissect the tonsils.	A
64	ENT Nasal snare	A hand-held manual surgical instrument intended to be inserted into the naris for the removal of tissue, typically polyps, tumours, and other abnormal tissue from the nasal cavity during ear/nose/throat (ENT) surgery	A
65	Otoscope, direct	A portable, battery-powered, hand-held device (non-endoscopic) primarily designed for examination of the outer ear canal and tympanic membrane (eardrum) by direct viewing through the ear opening.	A
66	Soft-tissue surgical forceps, alligator	A long, thin, hand-held manual surgical instrument designed to facilitate grasping and manipulation of soft-tissues/anatomical structures [typically during ear/nose/throat (ENT) surgery].	A
67	Ear, nose, and throat electric or pneumatic surgical drill	An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur for the controlled incision or removal of bone in the ear, nose, and throat area.	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (187) **Date:** 09 AUG 2021

Subject: Classification of medical device pertaining to Ophthalmology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants who intend to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

V.G.S.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC(187)
Drugs Controller General (India)
Directorate General of Health Services
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Notice

Classification of Medical Devices Pertaining to Ophthalmology

S. No.	Device Name	Intended Use	Risk Class
1	Adaptometer	An ophthalmic device intended to measure the time required for retinal adaptation and the minimum light threshold.	B
2	Amsler grid	An ophthalmic device intended to rapidly detect central and paracentral irregularities in the visual field.	A
3	Anomaloscope	A ophthalmic instrument used to test a patient for abnormal red/green colour vision by differentiating the red/green colour vision defects.	A
4	Aqueous/vitreous humour replacement medium kit	A collection of sterile devices, including a fluid or semifluid substance, used in combination to replace the fluid of the eye.	D
5	Automated lensmeter(Dioptometer)	An ophthalmic instrument designed to measure the focusing power (dioptric power) and other optical characteristics of a spectacle lens, contact lens, or prism.	A
6	Bagolini lens	An ophthalmic plane lens, intended to determine harmonious/anomalous retinal correspondence.	A
7	Binocular vision test unit	An ophthalmic device for binocular vision testing.	A
8	Blepharoplasty scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut eyelid tissue during plastic surgery of the eyelids (blepharoplasty).	A
9	Capsular bag anchor	A device intended to be permanently implanted in the posterior chamber of the eye for correction and fixation of a subluxated capsular bag, typically in association with in-the-bag intraocular lens (IOL) implantation.	C

10	Colour discrimination tester	An ophthalmic lamp, used to test a person's ability to differentiate between colours.	A
11	Colour-discrimination eye chart	Intended for testing colour vision.	A
12	Conjunctival scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut the conjunctiva and Tenon’s capsule on the eye surface to access the sclera.	A
13	Contact Lens (Including Coloured Contact Lens)	Device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage or/and to change the appearance of the eye for decorative purposes.	B
14	Contact lens agitation cleaning system	An assembly of devices used to clean and disinfect contact lenses through automated or manual mechanical agitation .	B
15	Contact lens disinfecting solution	An aqueous formulation containing appropriate agents for loosening debris from contact lenses, and that contains a disinfectant intended to act on contact lens.	B
16	Contact lens protein-removal solution	A formulation of proteolytic enzymes, used to remove debris and protein deposits from reusable contact lenses, or to remove protein deposits only.	B
17	Contact lens radius gauge	A measuring instrument used in ophthalmology to determine the radius of curvature of contact lenses.	A
18	Contact lens thermal cleaner	A unit intended to disinfect or sterilize reusable soft contact lenses by means of heat.	B
19	Corneal burr manual instrument	A hand-held, ophthalmic surgical instrument, used to excavate corneal tissue through manual rotation.	B
20	Corneal burr system	An assembly of devices designed for abrasion of the cornea and other eye tissues.	B
21	Corneal burr, abrasion	A device designed for abrasion of the cornea to polish corneal scratches and/or the pterygium bed after surgical removal, and/or for abrasion of lid margin lesions.	B
22	Corneal burr, rust ring removal	A device designed for gentle removal of rust stains (rust rings) from the cornea after the extraction of a ferrous foreign object.	B

23	Corneal epithelium perforator	Intended to create a number of small perforations in the epithelial layer of the cornea through which riboflavin can pass into the cornea during corneal collagen crosslinking, to treat corneal ectasia (typically keratoconus).	B
24	Corneal epithelium trephine	Intended to create a circular cut through the epithelial layer of the cornea to create an epithelial flap intended to be folded back during laser assisted epithelial keratomileusis (LASEK) surgery, after which the flap is replaced.	B
25	Corneal inlay, aperture reducing	A implantable device inserted into the natural cornea to treat presbyopia based on aperture reduction.	C
26	Corneal inlay, cornea-reshaping	A implantable device inserted into the natural cornea to treat refractive errors by reshaping the cornea.	C
27	Corneal light shield	A device, typically made of a non-abrasive fluid-absorbing material that is placed on the surface of the cornea to shield the retina from excessive illumination during an ophthalmic procedure.	B
28	Corneal marker	A manual instrument intended to be used to imprint, indent, and/or incise corneal tissue prior to an ophthalmic surgical procedure.	B
29	Corneal resection holder	A device designed to hold donated corneal tissue so that it can be resected in preparation for transplantation.	B
30	Corneal scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut corneal tissue.	B
31	Corneal shield	A mechanical eye shield made of collagen that is placed on the eye to protect the cornea.	B
32	Corneoscleral punch	A hand-held, manual ophthalmic surgical instrument designed to excise a segment of tissue from the sclera or cornea of a patient or from grafts taken from cadaver donors.	B
33	Diagnostic condensing lens	An ophthalmic lens used in binocular indirect ophthalmoscopy to focus reflected light from the fundus of the eye.	A
34	Donor cornea container	A receptacle intended to maintain, transport, and facilitate clinical examination of a donated cornea during the period between cornea collection and transplantation surgery.	C

35	Eikonometer	An ophthalmic instrument for diagnosing aniseikonia.	A
36	Electronic occlusion spectacles	An ophthalmic device designed to test and train vision for conditions where decreased visual acuity may be due to unequal vision in the eyes.	A
37	Endoscopic-imaging ophthalmic solid-state laser system	A device assembly intended to treat retinal and other eye disorders, such as glaucoma, during endoscopic cyclophotocoagulation (ECP) procedures.	C
38	Enucleation scissors	A hand-held, manual, ophthalmic surgical instrument used to cut tissue during eye surgery involving enucleation of the eye and/or its related structures.	A
39	Epiretinal/inner limiting membrane scraper	A hand-held manual surgical instrument intended to be used during posterior segment surgery to lift the inner limiting membrane (ILM) and/or an epiretinal membrane (ERM), and which may have additional posterior segment membrane manipulation uses.	B
40	Euthyscope	A modified ophthalmoscope that projects a bright light encompassing an arc of approximately 30 degrees on the fundus of the eye for the treatment of amblyopia.	A
41	Exophthalmometer	An ophthalmic instrument used to measure the degree of exophthalmos.	A
42	Eye cup	A receptacle designed to fit around the eye socket and which is filled with warm water or an eyewash solution and placed over the eye to allow the liquid to wash the affected eye.	A
43	Eye heat therapy pack	A device intended to be placed over closed eyes to apply heat for the treatment of meibomian gland dysfunction (MGD), dry eye syndromes, blepharitis and other related ocular conditions.	B
44	Eye irrigation shield	A device intended to be used with an eye irrigation kit/system to direct irrigation solution to the surface of the eye and allow the solution to gently lavage the surface of the eye.	A
45	Eye muscle clamp	An hand-held manual ophthalmic surgical instrument designed to atraumatically grasp and hold the extraocular muscles (EOM) during an ophthalmic surgical intervention.	B

46	Eye muscle sleeve	An implantable device made from synthetic materials that is used to encase or isolate an ocular muscle.	C
47	Eye pad	A sterile, cushion-like device intended to protect the eye or to absorb eye secretions.	A
48	Eye spud	A hand-held, manual, ophthalmic surgical instrument intended to be used to remove a foreign body/object embedded in or adhering to the surface of the eye globe.	A
49	Eye valve	An implantable device designed to regulate the flow of fluid between the anterior chamber and the space around the conjunctiva of the eye by allowing flow when the pressure in the chamber is above a pre-set value.	C
50	Eyelid clamp	A hand-held manual surgical instrument designed to atraumatically grasp and hold the eyelid during an ophthalmic surgical intervention.	A
51	Eyelid weight, external	An ophthalmic device that is applied to the outside of the upper eyelid to "lidload" the eyelid to restore upper eyelid muscle function.	A
52	Eyelid weight, implantable	An ophthalmic device that is implanted subcutaneously within the upper eyelid to "lidload" the eyelid to restore upper eyelid muscle function.	C
53	Felt tangent screen	A black tangent screen intended for assessing the extent of the patient's peripheral visual field by mapping the visual response to a test object moved from the periphery towards the centre of the screen.	A
54	Femtosecond ophthalmic solid-state laser system	A device assembly in which input energy is used to excite a glass/crystal rod to emit a high-power laser beam intended for ocular resections and incisions.	C
55	Fibreoptic general-purpose ophthalmic hook	A hand-held manual surgical instrument inserted into the eye during surgical intervention to manipulate anatomical structures or foreign bodies within the eye and simultaneously conduct a field of cold light to illuminate the surgical site.	A
56	Flieringa ophthalmic ring	A circular band, sutured to the sclera to prevent collapse of the globe during difficult intraocular operations.	A
57	Fornixscope	A manually-operated, ophthalmic device intended to provide indirect access and viewing of the upper conjunctival fornix and inner surface of	A

		the eyelid as an alternative to eyelid eversion.	
58	Fresnel lens	A very thin and flexible ophthalmic lens intended to be applied to the back of spectacle lenses to focus light to a focal point to help manage various vision conditions.	A
59	Fresnel prism	A device intended to be applied to spectacle lenses to give a prismatic effect typically to manage strabismus or other eye muscle dysfunction.	A
60	Fundus-imaging ophthalmic diode laser system	Intended for: ocular laser treatment procedures, including coagulation of abnormal retinal vasculature; and capturing real-time digital images of the anterior/posterior eye segments created using colour, fluorescein angiography and infrared imaging, for diagnosis/treatment planning.	C
61	Fundus-imaging ophthalmic solid-state laser system	Intended to coagulate abnormal vascular tissue in the retina and for other ocular photocoagulation procedures.	C
62	Glaucoma supraciliary implant	A non-bioabsorbable synthetic polymer device designed to be implanted in the supraciliary space (between the ciliary muscle/body and the sclera) for the restoration of aqueous humour outflow and subsequent reduction of intraocular pressure as part of treatment for open angle glaucoma.	C
63	Glaucoma therapy ultrasound system	A system designed to transduce radio-frequency (RF) electrical energy from a generator into ultrasound energy, for the extracorporeal application of high intensity focused ultrasound (HIFU) to the eye, to decrease aqueous humour production and reduce intraocular pressure (IOP)	C
64	Haidinger brush imager	An ophthalmic device designed to produce an image which facilitates his/her visual function evaluation, particularly the macular integrity.	A
65	Hand-held campimeter	A portable, hand-held device intended for assessing the central 30º visual field.	A
66	Hand-held telescope	A device that consists of an arrangement of ophthalmic lenses or mirrors with a handle intended to enlarge images for a visually impaired patient/person.	A

67	Hruby fundus lens	A 55 dioptre non-contact diagnostic ophthalmic lens intended for use in the examination of the vitreous body and the fundus of the eye under slitlamp illumination and magnification.	A
68	Implantable intraocular pressure monitoring system	An assembly of portable devices intended to continuously or regularly collect and display intraocular pressure (IOP) data for the diagnosis/monitoring of glaucoma.	C
69	Implantable iris prosthesis	An optical device intended to be implanted into the posterior chamber of the eye for the reconstruction of partial or total iris defects.	C
70	Indirect binocular ophthalmoscope	An ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see a wide angle, stereoscopic impression of the details of the fundus (retina) and other structures.	A
71	Intracorneal ring	An implantable, open-ended circular band designed to flatten the anterior corneal curvature, without disturbing the visual axis, to correct mild and moderate myopia.	C
72	Intranasal lacrimal neurostimulator	A hand-held device intended to be used in the home to provide electrical stimulation to sensory neurons of the nasal cavities to acutely increase tear production as treatment for aqueous deficient dry eye.	C
73	Intraocular pressure-reducing system	An assembly of manually-operated devices designed to reduce the intraocular pressure (IOP) by applying a controlled, external, mechanical compression to the surface of the eye in preparation for ophthalmic surgery.	C
74	Keratome	An ophthalmic surgical instrument intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.	B
75	Lacrimal tube	A implantable, single-lumen tube intended to provide tear drainage from the front surface of the eye, and also to facilitate saline solution irrigation to a paranasal sinus to manage chronic rhinosinusitis.	C
76	Lens spoon	A hand-held ophthalmic surgical instrument used in ophthalmic surgery to manipulate/remove the lens of the eye.	A

77	Maddox trial lens	A special ophthalmic trial lens in the form of a rod or series of rods (grooves/cylinders) that changes the size, shape, and colour of an image to dissociate the eyes in the evaluation of eye muscle dysfunction.	A
78	Mirror-prism spectacles	An optical device intended to enable the patient to see over the top of their head enabling them to look forward in the direction their head is pointing.	A
79	Nystagmus inducing optokinetic drum	An ophthalmic device intended to elicit nystagmus.	A
80	Nystagmus inducing tape	An ophthalmic device intended to be moved across a patient's field of vision to elicit optokinetic nystagmus and to test for blindness.	A
81	Ophthalmic calliper	A hand-held manual ophthalmic measuring instrument consisting of two legs hinged at one end and designed to measure the diameter, length, angles, and thicknesses of the eye.	A
82	Ophthalmic clip	A device typically made of a malleable metal (e.g., tantalum), intended to be implanted permanently or temporarily to bring together the edges of a wound, to aid in healing or to prevent bleeding from small blood vessels in the eye.	C
83	Ophthalmic cryosurgical system	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) to a target tissue for its destruction and removal during an ophthalmic surgical procedure.	C
84	Ophthalmic distometer	An ophthalmic instrument designed to measure the distance between the cornea and a spectacle or trial lens (vertex distance).	A
85	Ophthalmic dye laser system	A laser device assembly intended to coagulate abnormal vascular tissue in the retina, and for other photocoagulation procedures in the eye.	C
86	Ophthalmic excimer laser system	A laser device assembly intended for corneal ablation and other ophthalmologic procedures.	C
87	Ophthalmic head reflector	A head-worn ophthalmic device intended to reflect light onto the eye of a patient to allow examination of the eye and its associated structures.	A

88	Ophthalmic Irrigation Solution (Balanced Salt Solution)	Intended for the irrigation of the anterior chamber during cataract surgery and other intraocular or extraocular procedures or for the irrigation of the conjunctiva following application of fluoresceine or for moistening the corneal and conjunctival surface during laser treatment.	B
89	Ophthalmic noble gas laser system	A laser device assembly intended to coagulate abnormal vascular tissue in the retina and for other photocoagulation procedures in the eye.	C
90	Ophthalmic operating table top	A component of a modular operating table intended to provide support for and stabilization of the head of the patient (typically includes a headrest) and to help provide optimal access for the surgeon(s) during the intervention (e.g., by having a small-width table top and therefore a shorter stretch distance for the surgeon).	A
91	Ophthalmic soft-tissue surgical forceps	A hand-held manual instrument designed to grasp and manipulate intraocular tissues during ophthalmic surgery (e.g., anterior segment surgery, vitreo-retinal procedures, iridectomy, capsulorhexis).	B
92	Ophthalmic surgical device handling forceps	A hand-held manual surgical instrument with blades designed to grasp and manipulate a nonimplantable invasive ophthalmic surgical device (e.g., ophthalmic cannula, handless iris retractor) and/or for ophthalmic suturing.	A
93	Ophthalmic suture scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut suture during eye surgery.	A
94	Ophthalmic tonometer	An ophthalmic, measuring instrument designed for determining the intraocular pressure (IOP).	B
95	Ophthalmic ultrasound imaging system	An assembly of devices designed for ophthalmic ultrasound imaging procedures.	B
96	Ophthalmodiastimeter	An ophthalmic instrument for determining the proper distance at which to place prescription lenses for the two eyes.	A
97	Ophthalmoleukoscope	An ophthalmic device intended to be used for testing colour perception by means of colours produced by polarized light.	A

98	Ophthalmoscope	An ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see the details of the retina and other structures/media.	B
99	Optical pachymeter	An ophthalmic, device that uses optics to measure the thickness of the cornea.	A
100	Orbital depressor	A hand-held ophthalmic surgical instrument used to displace tissue to facilitate examination of the surrounding area in the orbital cavity during eye surgery.	A
101	Orbital rim prosthesis	An implantable ocular device used to reconstruct the floor of the bony cavity that contains the eyeball and its associated muscles, vessels, and nerves and is intended to house an artificial eye.	C
102	Perimeter	A diagnostic, ophthalmic instrument intended for assessing the extent of the patient's peripheral visual field.	A
103	Periocular/lacrimal retractor	A hand-held, non-self-retaining, ophthalmic surgical instrument intended to be used to separate periocular tissues and/or draw aside the margins of a periocular surgical wound during an ophthalmic intervention.	A
104	Phacoemulsification system	An assembly of ophthalmic devices intended to deliver energy through a dedicated handpiece tip, which is introduced through an incision made in the lens capsule, to perform phacoemulsification.	C
105	Phorometer	An ophthalmic instrument intended to be used to test ocular balance.	A
106	Phoropter	A mechanical ophthalmic device that is used during an ophthalmic examination; typically to determine a patient's prescription for glasses.	A
107	Pleoptophor	An ophthalmic instrument used for the treatment of eccentric eye fixation (casts in the eye) by dazzling the perimacular retina, thereby relatively enhancing the visual capabilities of the fovea.	A
108	Polatest	An ophthalmic device used for evaluating hidden (latent) squinting, i.e., when the patient is not aware of the condition, and also when it cannot be seen.	A
109	Ptosis sling	A sterile implantable device intended for the surgical correction of ptosis.	C

110	Pupillograph	A graphic recorder used for recording the response of the pupil to reflected light. It is used for ophthalmic diagnostic purposes.	A
111	Pupillometer	An ophthalmic instrument used for measuring the width or diameter of the pupil.	A
112	Retinal tack	A non-bioabsorbable, implantable device designed to permanently fix a detached retina to the underlying retinal pigment epithelium (RPE) during ophthalmic surgery.	C
113	Scleral buckling device	A device intended to be implanted on the sclera to compress the eye (scleral buckling) for the surgical treatment of retinal detachment.	C
114	Scleral expansion implant	A device designed for implantation in the sclera to produce expansion by altering the position of the underlying ciliary muscle.	C
115	Scleral marker	A manual instrument used to indent or imprint the surface of the sclera during an ophthalmic surgical or perioperative procedure.	B
116	Sclerotome	A hand-held manual ophthalmic surgical instrument that is knife-like in design and intended to be used to incise the sclera during a sclerotomy.	A
117	Scotometer	An instrument used for the recording and measuring of the areas of field of vision that is reduced, i.e., relative scotoma, or loss of sensitivity to light (absolute scotoma or blind spots).	A
118	Surgical binoculars	A pair of lenses intended to be mounted onto a surgeon's spectacles to function as small telescope and provide a magnified image of the visual field during patient examination or surgical intervention.	A
119	Symblepharon ring	An implantable device formed as a circular band used to help prevent the eyelid from adhering to the eyeball.	C
120	Synoptophor	A ophthalmic device used for the evaluation and training of a patient's binocular function.	A
121	Tachistoscope	An ophthalmic device designed to flash words or images at different speeds, for the purposes of ophthalmic diagnostic testing.	A
122	Ultrasound pachymeter	An ophthalmic device designed to use ultrasound to measure the thickness of the cornea, and may in addition be designed to measure axial length and anterior chamber depth.	B

123	Visual chart	An ophthalmic chart (Snellen chart) used in testing visual .	A
124	Visual light box	A light viewing box that uses a translucent version of the ophthalmic chart (Snellen chart) used for testing visual acuity.	A
125	Visual projector	An ophthalmic device intended to project an image on a screen to test visual acuity .	A
126	Visual evoked-potential electrode	An electrical conductor intended to record changes in the electrical potential for the purpose of measuring visual evoked responses.	A
127	Vitrectomy system	An assembly of ophthalmic devices intended to deliver energy through a dedicated hand-held instrument, typically used to treat diabetic vitreous haemorrhage, retinal detachment, epiretinal membrane, and macular hole.	C
128	Vitreous body prosthesis	A sterile bag/capsule intended to be implanted in the eye and filled with a fluid (not included) to replace the vitreous body and provide omnidirectional support of the retina for the treatment of severe retinal detachment.	C
129	Intraocular fluid	An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.	C
130	Intraocular gas	An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.	C
131	Intraocular lens guide	An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.	B
132	Ophthalmic refractometer	An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.	B

133	Keratoscope	A keratoscope is an AC-powered or battery-powered device intended to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope and videokeratoscope which records corneal curvature by taking photographs or videos of the cornea.	B
134	Contact Lens Inserter/Remover	A device designed to insert and remove contact lenses from the eye.	A
135	Ophthalmic working-channel cannula	A rigid tube designed to create a channel through the sclera for internal ocular access during posterior segment ophthalmic surgery. It is typically made of plastic materials or high-grade stainless steel and enables the introduction of ophthalmic surgical instruments; it may also be used for irrigation (i.e., the infusion of fluids to maintain the interior pressure of the eye during surgery). This is a reusable device.	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (150) **Date:** 23 AUG 2021

Subject: Classification of medical device pertaining to Pediatrics and Neonatology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants who intend to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File No. 29/Misc./03/2020-DC (150)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Pediatrics and Neonatology

S. No.	Name of Product	Intended Use	Risk Class
1	Aerosol tent, paediatric	A flexible enclosure designed to cover the bed of a infant or small child to provide an aerosolized environment of breathing gases/vapours, e.g., a suspension of medicated liquid or solid particles, for medication therapy. Typically used for the treatment of breathing disorders (e.g., asthma). It typically consists of a metal frame covered with transparent plastic, and wide bore tubing connected to the aerosol source and is used for the treatment of paediatric patients permitting them movement without restriction. This is a reusable device.	B
2	Airway Pressure / Oxygen Monitor	A mains electricity (AC-powered) device designed to continuously measure and display the breathing circuit pressure and oxygen (O2) concentration levels of respiratory gases delivered to a patient through positive pressure ventilation systems such as continuous positive airway pressure (CPAP) systems or ventilator respiratory circuits. It typically includes pressure and O2 level displays, alarms to signal pressure and O2 levels that exceed specified limits, and has connectors to allow attachment to the respiratory equipment; it is used for neonatal, paediatrics and adults. It may contain one or more rechargeable battery for independent/mobile use or when mains power is not available.	B
3	Anaesthesia Facemask, single use (paediatric)	A flexible, form-shaped device designed to be placed over a patient's nose and/or mouth to direct anaesthetic gases to the upper airway. It is intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. It may be stabilized with a headstrap. It is constructed of nonwoven materials such as conductive or non-conductive rubber, polyvinyl chloride (PVC), or other sterilizable materials that produce a soft, flexible cover to create an airtight seal against the patient's face. It typically includes a 15 mm connector (paediatric), and is available in a range of sizes. This device is sometimes used in association with a manual resuscitator. It is a single use, disposable device that is provided non-sterile.	B

4	Anaesthesia Facemask, reusable (paediatric)	A flexible, form-shaped device designed to be placed over a patient's nose and/or mouth to direct anaesthetic gases to the upper airway. It is intended to be worn by the patient/child to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. It may be stabilized with a headstrap. It is constructed of nonwoven materials such as conductive or non-conductive rubber, polyvinyl chloride (PVC), or other sterilizable materials that produce a soft, flexible cover to create an airtight seal against the patient's face. It typically includes a 15 mm connector (paediatric), and is available in a range of sizes. This device is sometimes used in association with a manual resuscitator. It is reusable.	B
5	Antimicrobial endotracheal tube, paediatric	A sterile hollow cylinder inserted orally or nasally into the trachea to provide an unobstructed airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation, and other situations where the patient is not properly ventilated, and which is coated with an antimicrobial agent [e.g., silver (Ag)] to help prevent infection. It may: 1) be packaged with a connector that will attach to a breathing circuit or manual resuscitator; 2) have a distal inflatable cuff to seal against the tracheal wall; 3) be radiopaque; and 4) have a built-in pilot balloon. It is available in various diameters and lengths for adult and paediatric patients. This is a single-use device.	C
6	Assistive ergonomic chair mobility base	A manually-operated, height-adjustable, non-powered, mobile support for an assistive ergonomic chair intended to be used by a healthcare provider/carer to provide mobility for a disabled (often paediatric) patient. It consists of a framework on wheels with a chair/seat mount, a handlebar for the user to hold/push the assembly, and may include a brake; it includes a manually-powered (fully or hydraulically-assisted) chair lifting mechanism. It is not a wheelchair component.	A
7	Breathing circuit gas-flow sensor, reusable	A device that includes a transducer intended to detect the movement of gases in a breathing circuit, and convert this into an electrical signal for relay to a ventilator (e.g., adult/paediatric/neonatal ventilators, anaesthesia system ventilators). It is connected to the breathing circuit and an appropriate data transfer cable and intended to enable the ventilator to display/monitor the gas flow to and from the patient, whereby controlled adjustments may be made. This is a reusable device.	C

8	Breathing circuit gas-flow sensor, single-use	A sterile device that includes a transducer intended to detect the movement of gases in a breathing circuit, and convert this into an electrical signal for relay to a ventilator (e.g., adult/paediatric/neonatal ventilators, anaesthesia system ventilators). It is connected to the breathing circuit and an appropriate data transfer cable and intended to enable the ventilator to display/monitor the gas flow to and from the patient, whereby controlled adjustments may be made. This is a single-patient device intended to be used for the duration of the treatment (single-use) before being discarded.	C
9	Cerebral oximeter	A mains electricity (AC-powered) photoelectric device that noninvasively measures the brain tissue blood oxygen saturation and venous oxygen saturation in the brain. It is typically used as an adjunct monitor for the regional haemoglobin oxygen saturation of blood in the brain of a paediatric or adult patient. It uses a cerebral sensor(s) having a light source and photodiode detector that is/are placed on the scalp/head. Position-1 detector detects infrared light absorption of extracranial blood and position-2 detector detects infrared light absorption of cerebral blood. Cerebral oxygenation is calculated by subtracting the absorption measured at site 1 from that measured at site 2.	C
10	Circulating-air whole-body heating/cooling system pad, reusable	An underlay or overlay through which heated or cooled air is circulated to heat and alternatively cool a patient's whole body (i.e., elevate or lower core body temperature) typically in surgical and intensive care settings. Air temperature and flow are regulated by a separate control unit. The device is available in a variety of lengths, widths, thicknesses, and shapes to accommodate body size and application (e.g., adult/paediatric, full-/partial-body). This is a reusable device.	B
11	Circulating-air whole-body heating/cooling system pad, single-use, sterile	A sterile underlay or overlay through which heated or cooled air is circulated to heat and alternatively cool a patient's whole body (i.e., elevate or lower core body temperature) typically in surgical and intensive care settings. Air temperature and flow are regulated by a separate control unit. The device is available in a variety of lengths, widths, thicknesses, and shapes to accommodate body size and application (e.g., adult/paediatric, full-/partial-body). This is a single-use device.	B

12	Circulating-fluid whole-body heating/cooling system pad, reusable	An underlay, overlay, or wrap(s) through which temperature-regulated fluid is circulated with the intention to heat and alternatively cool a patient's whole body (i.e., elevate or lower core body temperature) as part of a circulating-fluid whole-body heating/cooling system typically used in the operating room (OR), intensive care unit (ICU), or a recovery unit. The underlay/overlay is available in a variety of lengths, widths, and thicknesses to accommodate body size and application (e.g., adult/paediatric). It is intended to be used by a healthcare professional in a clinical setting. This is a reusable device.	B
13	Circulating-fluid whole-body heating/cooling system pad, single-use	A non-sterile underlay, overlay, or wrap(s) through which temperature-regulated fluid is circulated with the intention to heat and alternatively cool a patient's whole body (i.e., elevate or lower core body temperature) as part of a circulating-fluid whole-body heating/cooling system typically used in the operating room (OR), intensive care unit (ICU), or a recovery unit. The underlay/overlay is available in a variety of lengths, widths, and thicknesses to accommodate body size and application (e.g., adult/paediatric, full-/partial-body). It is intended to be used by a healthcare professional in a clinical setting. This is a single-use device.	B
14	Closed-ended adhesive infant/paediatric urine collection bag	A sterile, flexible plastic pouch with an adhesive flange (typically with a gender-specific shape) intended to be attached to the skin around the genitalia to collect urine from an infant/paediatric patient. It is not designed with an opening for urine drainage and is typically used for biochemical, cytological and/or bacteriological sampling. This is a single-use device.	B
15	Craniofacial bone screw, bioabsorbable	A small, sterile, threaded rod with a slotted head used for craniofacial bone (including the maxilla and/or mandible) fracture fixation by being screwed into bone to hold plates to bone or to provide direct interfragmentary stabilization of bone; it is made of a material that is chemically degraded and typically absorbed via natural body processes (e.g., degradable polymers). The device may be self-drilling/self-tapping. Its uses include repair of orbital fractures and fractures around the cranial sinuses, paediatric reconstructive surgery, and craniotomy flap fixation.	D

16	Craniofacial bone screw, non-bioabsorbable, sterile	A small, sterile, threaded rod with a slotted head intended to be implanted or inserted short-term in craniofacial bone (including the maxilla and/or mandible) for fracture fixation by direct interfragmentary stabilization of bone or by screwing plates in place; it may also be intended for transplanted bone fixation. It may be self-drilling/self-tapping and is made of a material that is not chemically degraded or absorbed via natural body processes [e.g., implant grade metal such as titanium (Ti)]. Its uses include repair of orbital fractures and fractures around the cranial sinuses, paediatric reconstructive surgery, craniotomy flap fixation, bone augmentation procedures.	C
17	Electric pad whole-body heating system	An assembly of mains electricity (AC-powered) devices designed to heat a patient's whole body, to compensate for the loss of normal body heat, with heat generated from an externally applied pad typically containing electrical heating elements or cables. The system includes the pad designed to heat under or over the patient, and a control unit to regulate and monitor the heat. The pads are available in a variety of lengths, widths, and thicknesses to accommodate body size and applications (e.g., adult/paediatric, full-/partial-body). The system is typically used in the operating room (OR), the intensive care unit (ICU), or in neonatal and recovery units.	B
18	Electric pad whole-body heating system pad	An electrically-heated underlay or overlay intended to provide heat under or over a patient as part of an electrical heating pad system used to heat a patient's whole body (i.e., elevate core body temperature) typically in surgical and intensive care settings. The underlay/overlay typically contains electrical heating elements or cables supplied with energy by a dedicated control unit. The underlay/overlay is available in a variety of lengths, widths, and thicknesses to accommodate body size and application (e.g., adult/paediatric, full-/partial-body). This is a reusable device.	B
19	Enteral feeding kit, adult/paediatric, sterile	A collection of sterile devices that includes tubing and other materials intended to administer nutrient liquids directly into the stomach, duodenum, or jejunum of an adult or paediatric (excludes infants) patient by means of gravity or an enteral pump. This is a long term use device.	B

20	Exhaled-gas oesophageal intubation detector, paediatric	A device designed to verify proper endotracheal (ET) tube placement by detecting/assessing escaping levels of exhaled carbon dioxide (CO2) during airway management disclosing potential incorrect intubation. It is used during paediatric intubation and is attached between the ET tube and the breathing device. It typically functions through colorimetric CO2 detection using an indicator paper that changes colour. A colour chart (e.g., attached to the device) permits interpretation into approximate CO2 concentration. It is used in healthcare facilities or in the field to evaluate oesophageal intubation, which if performed incorrectly, prevents patient ventilation. This is a single-use device.	A
21	External counterpulsation system, paediatric	A noninvasive, stationary assembly of devices intended to assist the blood circulation of a paediatric patient suffering from heart disease through the electrocardiogram (ECG) synchronized inflation of pressure cuffs worn around the extremities/buttocks. It includes a patient bed with attached inflatable cuffs, an air pump, ECG cables, a control unit with dedicated software, and may include additional monitoring devices (e.g., pulse oximeter probe). The cuffs are intended to inflate from the most distal (e.g., lower leg) to the most proximal (e.g., buttocks) during diastole and deflate during systole to achieve increased preload and decreased afterload.	B
22	External defibrillator electrode, paediatric, reusable	An electrical conductor used in pairs to transmit a controlled electrical shock from an external defibrillator to a pre-pubescent patient in order to defibrillate the heart (restore a normal rhythm) or slow a rapid heart rate. It usually consists of a cable set that terminates with small-diameter, hand-operated electrodes (paddles) that are held by the operator to the chest (the intact torso) of the patient so that the discharge passes across the region of the heart. Typically available as a set of two electrodes with a combined cable/connector, or as a single electrode with cable/connector, in which case two will be connected to the external pulse generator (EPG). This is a reusable device.	B
23	External defibrillator electrode, paediatric, single-use	An electrical conductor used in pairs to transmit a controlled electrical shock from an external defibrillator to a pre-pubescent patient in order to defibrillate the heart (restore a normal rhythm) or slow a rapid heart rate. It typically consists of a cable set [with a connector for insertion into the external pulse generator (EPG)] that terminates with small-diameter, self-affixing pads (the electrodes) prefabricated with contact gel and an adhesive, that are applied to the chest (the intact torso) of the patient so that the discharge passes across the region of the heart. This device may remain applied to the patient during stages of treatment. This is a single-use device.	B

24	Flexible bone nail, non-sterile	A non-sterile, bending rod made of metal designed for insertion into the intramedullary canal of a long bone for fracture fixation where flexibility of the implant is desired. It is available in various lengths and diameters for use on lower and upper extremity diaphyseal fractures, and some metaphyseal fractures of paediatrics and small-statured/normal adults, to provide temporary stabilization of the bone segments/fragments until bone consolidation has been achieved. It is intended to splint the cortices and maintain elastic energy to continually brace against rotational/angular forces of the muscles. This is a single-use device intended to be sterilized prior to use.	C
25	Flexible bone nail, sterile	A sterile, bending rod made of metal designed for insertion into the intramedullary canal of a long bone for fracture fixation where flexibility of the implant is desired. It is available in various lengths and diameters for use on lower and upper extremity diaphyseal fractures and some metaphyseal fractures of paediatrics and small-statured/normal adults to provide temporary stabilization of the bone segments/fragments until bone consolidation has been achieved. It is intended to splint the cortices and maintain elastic energy to continually brace against rotational/angular forces of the muscles. This is a single-use device.	C
26	Funnel chest remodelling bar	A non-sterile implantable device intended to be used to reduce the deformity of pectus excavatum (funnel chest) by applying outward force from a position deep to the sternum to reposition the sternum; it is typically used in paediatric patients and surgically removed when remodelling is evident (after 2-3 years). It is a thin curved bar, with or without serrations, made of metal [e.g., stainless steel, titanium (Ti)] that can be anchored with wires or with stabilizer plates laterally on the rib cage; devices associated with implantation may be included. This is a single-patient device intended to be sterilized prior to use.	C
27	Growth-correction orthopaedic fixation plate kit	A collection of implantable devices used to redirect the angle of growth of long bones in paediatric patients where the growth plates (epiphysial cartilage) are not fused, to allow for the gradual correction of congenital or acquired deformities (e.g., valgus, varus, or flexion deformities of the knee, ankle, or elbow). It typically includes various-sized sheets of surgical steel or titanium alloy, and bone screws to attach the sheets to the bone surface over the growth plates. The screws may be allowed to swivel in their position so that the implant acts like a hinge, permitting growth at the growth plate to gradually straighten the limb.	C

28	Hepatic ultrasound elastography system applicator	A non-sterile hand-held device designed to be used for the transcutaneous measurement of liver stiffness based on transient elastography. It includes an ultrasound transducer and an electrodynamic transducer intended to generate a controlled transient vibration that produces a mechanical elastic shear wave propagated through the skin and liver; subsequent ultrasound measurements can be used to calculate a measure of liver stiffness/ultrasonic attenuation of tissues. The device is designed to connect to a control unit and may be available in various forms for different applications [e.g., paediatric, bariatric (obese)]. This is a reusable device.	B
29	Infant apnoea monitor	A mains electricity (AC-powered) device that is used to register the respiratory rate of an infant and which gives an alarm signal (e.g., audible/visual) when the pre-set limits are exceeded caused by an extended interruption or cessation (apnoea) of the infants breathing pattern; a condition known as sudden infant death syndrome (SIDS). This will alert the infant's parent(s), child-minder or hospital staff when such life-threatening episodes occur. This device is usually connected to some form of movement sensing device, e.g., small pads placed directly under the infant or belts with sensors around the chest. It can be designed for use in the hospital/institution, or for home-use.	C
30	Infant bed crib top	A covering made of a metallic, plastic, or metallic/plastic combination structure designed for secure/permanent attachment to the top of an infant bed (i.e., a cradle or crib) to protect the infant from accidental damage. Commonly called a crib top, it is typically a rigid structure with a flexible, transparent plastic (e.g., vinyl) covering around it forming a canopy that encloses the bed.	B
31	Infant bed restraint	A device designed to limit totally or partially the movement of infants and/or toddlers when lying in its bed or crib; this may be a belt or a strap, or to prevent them from falling out of a bed after climbing the bedrail (e.g., a cover or net). This is a reusable device.	B
32	Infant care table	A specially made table used for nursing, e.g., washing or changing of nappies, of newborn babies. It can be equipped with a washing basin, typically of soft material (rubberized cloth), and a surface upon which to lie the infant for drying with a towel.	A
33	Infant heat shield	A protective guard intended to be used to reduce heat loss due to insensible water loss, i.e., evaporation, during the radiant warming of primarily premature infants. This is a single-use device.	B

34	Infant incubator control unit	An electronic unit that is used to monitor and regulate the important temperature and environmental features of an infant incubator. It will be connected to the mains electricity (AC-powered) when the incubator is stationary, but will be powered by a battery pack if the incubator is in transport. This device is usually interchangeable with other incubators of the same type.	C
35	Infant incubator warming hood	A heating element positioned above an incubator's chamber designed to provide warmth for the chamber's environment. It may be used instead of or as a supplement to the incubator's internal heating system, and may be built onto or be an integral part of the incubator hood.	A
36	Infant inguinal hernia truss	A bandage-like strap of worsted yarn intended to be worn over the groin to prevent protrusion of abdominal contents in an infant with an inguinal hernia. This is a single-use device.	A
37	Infant limb immobilizer, reusable	A non-rigid device, usually made of a fabric and/or plastic materials, used to temporarily render parts of an infant's body immovable, e.g., the arms and/or feet while the patient undergoes therapeutic or diagnostic interventions. It will typically be used to prevent the patient from interrupting an intravenous (IV) infusion, pulling out a catheter, or interfering with wound care. This is a reusable device.	A
38	Infant limb immobilizer, single-use	A non-rigid device, usually made of a fabric and/or plastic materials, used to temporarily render parts of an infant's body immovable, e.g., the arms and/or feet while the patient undergoes therapeutic or diagnostic interventions. It will typically be used to prevent the patient from interrupting an intravenous (IV) infusion, pulling out a catheter, or interfering with wound care. This is a single-use device.	A
39	Infant resuscitation cabinet	A small chamber, usually wall-mounted, used for the emergency resuscitation of newborn infants who do not breathe spontaneously at birth and are oxygen deficient. It typically has a front door or lid that folds out to serve as a surface upon which the infant is placed. It is typically equipped with a heating lamp, a low-pressure suction system, an oxygen (O2) supply, a gas mixer (oxygen/air), and a resuscitator. It may be supplied with the resuscitation devices or empty, in which case the resuscitation devices are fitted by another party (e.g., hospital clinical engineer, device supplier).	B

40	Infant resuscitation table	A flat surface fixed on legs and on which newborn infants who do not breathe spontaneously at birth and are oxygen deficient are placed for emergency resuscitation. It is typically equipped with a heating lamp and sometimes a supplemental heating pad, a low-pressure suction system, an oxygen (O2) supply, a gas mixer (oxygen/air), and a resuscitator. It may be supplied with the resuscitation devices or not, in which case the resuscitation devices are fitted by another party (e.g., hospital clinical engineer, device supplier). This device is typically fixed in one place.	B
41	Infant scale, electronic	An electrically-powered device designed to measure the weight of an infant, particularly a newborn, or to monitor weight changes, e.g., during critical care procedures. It typically consist of a weight tray, a flexure plate or bending beam, an electronic transducer, and an analogue or digital display; it may include markings to also measure infant length. The device is also known as paediatric or baby scale.	A
42	Infant sleep positioner	A non-rigid device, usually made of flame retardant fabric and/or polyurethane foam materials, intended to modify the sleeping position/posture of infants to prevent deformational plagiocephaly, a flattening of the back of the skull from a consistent back-sleeping position. It is available in a variety of designs including a wedge-shaped head pillow, a sleeping garment (sleeveless vest) with hooks/Velcro fasteners/nylon zip fasteners and an insertable foam wedge, or a specially designed mattress. This is a reusable device.	A
43	Infant warmer	A mains electricity (AC-powered) mobile device that contains an infrared (IR) heating element(s) designed to emit controlled, evenly distributed overhead heat to the body of a newborn/infant patient requiring supplemental heat. This device is equipped with wheels so that it can easily be moved to different areas of a room, ward, or department.	C
44	Infant whole-body immobilizer, reusable	A device intended to be used to temporarily render an infant's whole body immovable (strait-jacket effect) while the patient undergoes therapeutic or diagnostic interventions. It includes non-rigid fabric and/or plastic components but might also include a rigid structural component (e.g., board). This is a reusable device.	A
45	Infant whole-body immobilizer, single-use	A non-sterile, non-rigid device, usually made of a fabric and/or plastic materials, intended to be used to temporarily render an infant's whole body immovable (strait-jacket effect) while the patient undergoes therapeutic (e.g., phototherapy) or diagnostic interventions. This is a single-use device.	A

46	Infant/regional-body warmer	A mains electricity (AC-powered) device that contains an infrared (IR) heating element(s) designed to emit controlled, evenly distributed heat to a newborn/infant patient requiring a supplemental regulated thermal environment, or to provide heat to the limbs of a more mature person, typically an adult, who has been severely burned or who is undergoing a procedure. This is a stationary device that is generally operated at a single site.	C
47	Infant-hammock bed mattress	A foam-filled case with a central meshed/netted depression/hole designed to be placed in a cot/crib/bassinet/bed/incubator and to cradle a young infant during sleep/rest, and can used for phototherapy, transportation and burns patients. It is available in various shapes and sizes and is not intended to be placed on an existing mattress. The breathable netting is intended to help reduce the risk of infant injuries/disorders such as suffocation, flat head (plagiocephaly), sudden infant death syndrome (SIDS), pressure sores, and hyperthermia. This is a reusable device.	A
48	Infant-hammock bed mattress overlay	A portable pad with a central meshed/netted depression designed to be placed on a cot/crib/bed mattress and to cradle a young infant during sleep/rest. The device is typically foam-filled and wedge-shaped with ventilation channels and securing ribbons. The breathable netting is intended to help reduce the risk of infant injuries/disorders such as suffocation, flat head (plagiocephaly), sudden infant death syndrome (SIDS), and hyperthermia. This is a reusable device.	A
49	Internal defibrillator electrode, paediatric	An electrical conductor used in pairs to transmit a controlled electrical shock from an external defibrillator directly to the exposed heart muscle of a pre-pubescent patient in order to intentionally stop/start the heartbeat during cardiopulmonary surgery. It usually consists of a cable set with small-diameter, spoon-like electrodes (commonly known as internal defibrillator paddles or spoons) that are held by the operator directly to either side of the heart muscle so that the discharge passes directly through the heart. It is typically available as a set of two electrodes with insulated handles with a combined cable/connector. This is a reusable device.	C
50	Lacrimal intubation set	A collection of sterile devices designed to prevent/treat obstruction of and drain tears from the lacrimal ducts. It typically consists of a cannula for insertion into the lacrimal ducts, a tube (e.g., silicone) to perform various ocular irrigation or aspiration procedures (e.g., lacrimal syringing), and a probe to remove ductal obstructions. It can be used for adult and paediatric patients, particularly to treat canalicular pathologies (stenosis, obstruction, wounds, imperforation of the lacrimo-nasal canal in the infant), for prevention of viral and post-chemotherapy stenoses, or for dacryocystorhinostomy (DCR). This is a single-use device.	C

51	Liquid crystal vein locator	A non-sterile device designed to measure skin temperature at several different points using liquid crystal sensors (usually formed from esters of cholesterol which are sealed in a plastic band) placed on the skin around the forearm in order to assist a healthcare professional to locate peripheral veins in a patient before venipuncture. The device is used in paediatric, geriatric, and other patients with hard-to-find veins. This is a single-use device.	B
52	Microlaryngeal probe	A hand-held manual surgical instrument designed for paediatric laryngology and for phonatory microsurgery applications in adults. This delicate probe gives a precise sense of palpation for accurate detection of induration, tissue mass, and cystic changes. It is also used to break thick mucus fluid before its extraction. This is a reusable device.	A
53	Multifunction cardiac electrode, paediatric	A non-sterile electrical conductor designed to be applied to a paediatric patient for automatic or manual defibrillation, external pacing, cardioversion, and electrocardiographic monitoring through transmission of cardiac bioelectric signals (typically from the thoracic surface) to devices that record/process the signals and potentially return electrical impulses [e.g., electrocardiograph, electrocardiographic monitor(s), defibrillator]. It is a disk-like electrode that is affixed to the skin with a special adhesive and a conductive gel (pre-gelled). It may be made of x-ray translucent materials and may include permanently attached lead wires. This is a single-use device.	C
54	Neonatal chest percussor	A hand-held battery-powered device (a percussor) intended to be operated by a healthcare professional to provide external vibrations to the chest wall of a neonate to help loosen bronchial mucus for expectoration through suctioning. It is small enough in physical dimension and weight to be operated inside an infant incubator and has a percussion head suitable for the thorax of a neonate. It is used to help loosen secretion build-up in the lungs of neonates who cannot perform the natural cough mechanism.	B
55	Neonatal CPAP unit	A mains electricity (AC-powered) device, which may include rechargeable batteries, intended to assist noninvasive ventilation (i.e., without use of an artificial airway) of a neonatal/infant patient via an attached nasal cannula or mask, using continuous positive airway pressure (CPAP) during spontaneous respiration. It is an electronic unit with controls, and may be used with compressed medical gas cylinders [e.g., air, oxygen (O2)] or include an O2 concentrator compartment; additional features (e.g., adjustable flow rates and O2 concentration, humidification) may be provided. It is primarily intended for use in a healthcare facility, especially in intensive and critical care settings.	C

56	Neonatal electrocardiographic electrode	A non-sterile electrical conductor applied to a neonatal patient to transmit electrical signals from the body surface to a data measuring/display device (typically an electrocardiograph, patient monitor, or patient monitoring system) to produce an electrocardiogram (ECG). This is a single-use device.	B
57	Neonatal hypothermia cot	An assembly of non-powered devices intended to induce and sustain mild hypothermia in a neonatal patient to treat hypoxic-ischemic encephalopathy (HIE). It consists of an insulated cradle, a heat-retention pad(s), and a patient-contact heat-conduction mattress. The heat-retention pad(s) is intended to be cooled in a refrigerator prior to use, and is constructed of a phase change material designed to help maintain patient hypothermia for a prolonged period. This is a reusable device.	B
58	Neonatal hypothermia cot heat-conduction mattress	A non-sterile, patient-contact component of a neonatal hypothermia cot assembly intended to be used during induction of mild hypothermia in a neonatal patient by allowing heat transfer away from the recumbent patient. It is typically gel-filled and intended to be placed between the patient and a cooled heat-retention pad. This is a reusable device.	B
59	Neonatal hypothermia cot heat-retention pad	A non-sterile, non-powered component of a neonatal hypothermia cot assembly intended to be used to induce and sustain mild hypothermia in a neonatal patient to treat hypoxic-ischemic encephalopathy (HIE). It is intended to be cooled in a refrigerator prior to use, and is constructed of a phase change material designed to retain heat and help maintain patient hypothermia for a prolonged period. This is a reusable device.	B
60	Neonatal intensive-care ventilator	A mains electricity (AC-powered) automatic cycling device intended for short-term and long-term ventilatory support for a neonatal/paediatric patient, especially those preterm and critically ill with respiratory failure in a critical care setting. It is typically a time-cycled, pressure-control device that includes a small bore flexible tube breathing system. It may be capable of high frequency oscillatory ventilation in addition to conventional ventilation, and includes positive end-expiratory pressure (PEEP) and continuous positive airway pressure (CPAP) controls.	C
61	Neonatal kangaroo care garment	A non-sterile, upper body garment intended to allow a parent to safely carry/support their premature, dysmature, and/or sick infant in a manner which enables skin-to-skin contact between parent and infant (kangaroo care). It typically consists of a wrap/sweater with a variety of straps, and pockets to accommodate ventilation, monitoring, feeding, and warming devices. This is a reusable garment.	A

62	Neonatal physiologic monitoring system	A device assembly designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care. It is typically capable of monitoring parameters such as electrocardiogram (ECG), respiration rate, heart rate, blood pressure, and body temperature; it may also assess haemoglobin oxygen saturation (SpO2) through transcutaneous sensors that measure both transcutaneous oxygen (tcPO2) and transcutaneous carbon dioxide (tcPCO2) saturation. The system typically includes sensors with appropriate size and design for infant use.	C
63	Neonatal pulmonary surfactant catheter	A sterile, flexible, single-lumen tube intended to be introduced into the trachea of a neonate for the administration of exogenous surfactant as part of pulmonary surfactant therapy. It may have a curved distal end to assist navigation into the trachea, and is usually used to treat neonates at a high-risk of infant respiratory distress syndrome [surfactant deficiency disorder (SDD)]. This is a single-use device.	A
64	Neonatal/paediatric heart rate monitoring application software	An application software program intended to be installed in an off-the-shelf computer to acquire, record, measure and analyse an electrocardiogram (ECG) signal or heart rate data from a physiological monitor. It typically detects variations in heart rate [e.g., decelerations, reduced baseline heart rate variability (HRV)] in real-time, and is typically used in the neonatal or paediatric intensive care unit (ICU). This device is typically identified by a proprietary name and "version" or "upgrade" number.	C
65	Neonatal/paediatric heart rate monitoring hardware	A mains electricity (AC-powered) device designed to be connected between a physiological monitor and an off-the-shelf computer, containing dedicated application software, and intended to function as a data acquisition node for real-time sampling of neonatal/paediatric patient electrocardiogram (ECG) waveforms for communication to the software for analysis of variations in heart rate. It typically consists of a microprocessor, random access memory (RAM), and analogue-to-digital sampling card, and is typically used in the neonatal or paediatric intensive care unit (ICU).	C
66	Nitric oxide delivery unit, system-based	A mains electricity (AC-powered) device, which may include internal rechargeable batteries, intended for the delivery of precise amounts of nitric oxide (NO), also known as nitrogen monoxide, to the respiratory tract of neonate, paediatric, and adult patients to treat severe respiratory disorders [e.g., primary pulmonary hypertension (PPH), acute respiratory distress syndrome (ARDS)]. It consists of a portable main unit that enables the delivery and monitoring of NO to gases that are to be breathed by the patient via a ventilator or other respiratory device/system. It typically includes accessory items (e.g., tubing, filters) and possibly a trolley (cart) for mobility.	C

67	Non-rechargeable public semi-automated external defibrillator electrode, paediatric	An electrical conductor, with integral batteries and regulated by a dedicated external pulse generator (EPG), designed to create an electrical shock(s) and defibrillate the heart (restore normal rhythm) to treat ventricular fibrillation or pulseless ventricular tachycardia in a pre-pubescent patient. It is a cartridge-type electrode, in pairs, with non-rechargeable batteries that provide the energy to produce the electrical shock(s) after its adhesive pads are placed on the skin of the patient. This is a single-use device that is replaced after a patient application or after elapse of its expiry date.	B
68	Open-ended adhesive infant/paediatric urine collection bag	A sterile, flexible plastic pouch with an adhesive flange (typically with a gender-specific shape) intended to be attached to the skin around the genitalia to collect urine from an infant/paediatric patient. It is designed with an opening for urine drainage and is typically used for urine output measurement. This is a single-use device.	A
69	Open-surgery manual linear cutting stapler, reprocessed	A sterile, hand-held, manual surgical instrument intended to be used during open surgery (including abdominal, gynaecological, paediatric, or thoracic surgery) for the expeditious transection/resection of tissues and creation of anastomoses. It operates by a manual mechanism whereby it cuts the tissues (e.g., colon) and simultaneously applies single or multiple linear rows of surgical staples to the resulting ends, eliminating the need for temporary clamping. The staples and cutting blade may be housed in a single-use loading unit (SULU) which may be included. This is a previously used single-use device that has been processed for an additional single-use patient application.	C
70	Open-surgery manual linear cutting stapler, reusable	A hand-held, manual surgical instrument intended to be used during open surgery (including abdominal, gynaecological, paediatric, or thoracic surgery) for the expeditious transection/resection of tissues and creation of anastomoses. The device operates by a manual mechanism (e.g., lever, sliding knob) whereby it cuts the tissues (e.g., colon) and simultaneously applies single or multiple linear rows of surgical staples to the resulting ends, eliminating the need for temporary clamping. The staples and cutting blade may be housed in a single-use loading unit (SULU) which may be included. This is a reusable device intended to be sterilized prior to use.	C

71	Open-surgery manual linear cutting stapler, single-use	A sterile, hand-held, manual surgical instrument intended to be used during open surgery (including abdominal, gynaecological, paediatric, or thoracic surgery) for the expeditious transection/resection of tissues and creation of anastomoses. The device operates by a manual mechanism (e.g., lever, sliding knob) whereby it cuts the tissues (e.g., colon) and simultaneously applies single or multiple linear rows of surgical staples to the resulting ends, eliminating the need for temporary clamping. The staples and cutting blade may be housed in a single-use loading unit (SULU) which may be included. This is a single-use device.	C
72	Open-surgery manual linear stapler, reusable	A hand-held, manual surgical instrument intended to be used during open surgery (including abdominal, gynaecological, paediatric, or thoracic surgery) for the application of surgical staples to approximate internal soft tissues (e.g., two ends of bowel) or for fixation of a surgical mesh to tissue. The device operates by a manual mechanism (e.g., lever, sliding knob) whereby it applies single or multiple linear rows of surgical staples to a portion of tissue; it has no cutting function. The staples may be housed in a single-use loading unit (SULU) which may be included. This is a reusable device intended to be sterilized prior to use.	C
73	Open-surgery manual linear stapler, single-use	A sterile, hand-held, manual surgical instrument intended to be used during open surgery (including abdominal, gynaecological, paediatric, or thoracic surgery) for the application of surgical staples to approximate internal soft tissues (e.g., two ends of bowel) or for fixation of a surgical mesh to tissue. The device operates by a manual mechanism (e.g., lever, sliding knob) whereby it applies single or multiple linear rows of surgical staples to a portion of tissue; it has no cutting function. The staples may be housed in a single-use loading unit (SULU) which may be included. This is a single-use device.	C
74	Ophthalmic tonometer, battery-operated	An ophthalmic, battery-powered, measuring instrument designed for determining the intraocular pressure (IOP) by exerting an external force against the eye which provides a reading of the resistance of the tunica of the eye to deformation (the extent of corneal indentation) which is expressed in millimetre(s) of mercury (mmHg). This hand-held device (known as a contact type, e.g., a Perkins tonometer) is often used for, e.g., the examination of postoperative, bedridden and paediatric patients.	B

75	Orthopaedic medialization instrument	A surgical instrument used to restore the anatomical and mechanical axes during orthopaedic correction osteotomies. It is typically designed as a robust block with a long, thin, adjusting rod running through its centre and an incremented measuring scale that enables the surgeon to gauge the adjustments made to the axes (the medialization). It is usually attached to a dedicated bone plate which is bridging the osteotomy site in order to achieve the correct offset of the two separated bone sections. It is typically made of high-grade stainless steel and can be used on adult and paediatric patients. This is a reusable device.	B
76	Oxygen administration hood, paediatric	A device consisting of a rigid/semi-rigid transparent plastic shell that forms an enclosure over an infant's whole body, or the head only, in order to provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake. It is connected to an O2 source and may be used concurrently with increased humidification and temperature control. It is designed to be used for patients adverse to oxygen delivery devices such as a nasal cannula or face mask. This device may include the tubing, a diffuser (to disperse the flow of incoming O2), O2 concentration and humidity sensors. This is a reusable device.	A
77	Oxygen administration tent, neonatal/paediatric	A flexible enclosure designed to cover the bed of a neonatal or small child to provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake. It is connected to an O2 source and may be used concurrently with increased humidification and temperature control. It typically consists of a metal frame covered with transparent plastic, the tubing, and may have built-in humidification. It is used for the treatment of breathing disorders in infant and paediatric patients permitting them movement without restriction. This is a reusable device.	A
78	Paediatric bed	A bed with appropriate size for children (typically up to 12 years of age) that incorporates safety canopy tops, fixed endrails, and moveable and latchable siderails. It allows children complete freedom in bed without the danger of falling out, yet allows staff access to the patient. Paediatric beds are not appropriate for neonates/infants.	B
79	Paediatric blood donor set	A sterile assembly consisting of multiple collection containers (typically five connected flexible bags) of smaller volume than those used in adult sets. It is used for the storage of adult donor blood which is decanted from a normal adult size pack into this device in order to create smaller paediatric volume packs for infusion. The individual paediatric packs are then separated and sealed for later infusion. This is a single-use device.	B

80	Paediatric cardiopulmonary bypass cannula	A sterile tube intended to be used during open heart surgery on a paediatric patient (e.g., neonatal, infant) to access the arterial or venous vasculature surrounding the heart (i.e., intended for both venous and arterial access), to serve as a channel intended to be connected to an extracorporeal circuit for the transport of blood to or from a cardiopulmonary bypass system (heart-lung machine) circuit where the blood is pumped and oxygenated. It is typically a reinforced polymer tube which may include accessories/devices dedicated to introduction/function (e.g., introducer/connector). This is a single-use device.	C
81	Paediatric dental chair, electric	A mains electricity (AC-powered) device designed to support a paediatric patient in a seated position to facilitate dental examination, treatment, and/or minor surgery procedures. It is typically adjustable in height to enable healthcare staff to perform procedures while standing. It usually includes head and armrests, a reclining back that may be tilted from a vertical to a horizontal position, and has rotating capabilities; some types can be programmed to several standard positions. Devices intended for dental examination and/or treatment (e.g., lights, irrigation) may be attached as components of the chair, or stand separately as self-supported, wall- or ceiling-mounted units.	B
82	Paediatric dental chair, mechanical	A manually- or hydraulically-powered device designed to support a paediatric patient in a seated position to facilitate dental examination, treatment, and/or minor surgery procedures. It is typically adjustable in height to enable healthcare staff to perform procedures while standing. It usually includes head and armrests, a reclining back that may be tilted from a vertical to a horizontal position, and has rotating capabilities; some types can be programmed to several standard positions. Devices intended for dental examination and/or treatment (e.g., lights, irrigation) may be attached as components of the chair, or stand separately as self-supported, wall- or ceiling-mounted units.	B
83	Paediatric dorsiflexion slant board	A standing platform for a child designed to slant the surface on which the feet are placed to create a slope angle to therapeutically stretch the ankle plantar flexion muscles/tendons. It is intended to be used in the treatment of various medical conditions (e.g., congenital, neurological, post-traumatic) where tendon tightness and muscle contracture affect the ability to dorsiflex the foot, possibly leading to an abnormal gait. It is typically made of synthetic polymer materials. This is a reusable device.	A

84	Paediatric strabismus screening scanner	An electrically-powered optic device designed for screening for strabismus and amblyopia risk in children (aged 2 to 8 years) by using retinal reflections of polarized laser light to/from both eyes simultaneously. It consists of a self-contained unit which includes a visually enticing interface for the child to look at, and provides a result, in the form of a recommendation for referral to an ophthalmologist, if an abnormality is detected.	B
85	Paediatric urine collection/analysis kit	A collection of devices intended to be used to collect and analyse a paediatric urine specimen for multiple clinical chemistry analytes (e.g., ketones, glucose and pH). It consists of a specimen collection undergarment (nappy or diaper) worn by the patient, and quantitative test strips for various clinical chemistry analytes. Results are analysed visually or with dedicated interpretive software (not included). It is intended to be used at the point-of-care by a healthcare professional, or at home by a caregiver. This is a single-use device.	A
86	Paediatric-temperature nasogastric/orogastric tube	A sterile, thin, flexible, hollow cylinder designed as a paediatric or neonatal enteral feeding tube with an integrated temperature sensor that continuously measures oesophageal temperature. It is typically intended to provide gastric feeding or deliver oral medication via a nasogastric or orogastric route, and to capture the oesophageal temperature for a period (e.g., up to 30 days) via a thermistor sensor located near the distal tip. It is available in various diameters and may connect to a compatible patient monitoring device. This is a single-use device.	B
87	Polyglyconate suture	A sterile, single-strand (monofilament), synthetic, bioabsorbable thread made from polyglyconate (prepared from a copolymer of glycolic acid and trimethylene carbonate) intended to join (approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues (especially in paediatric cardiovascular surgeries). It may include an attached needle intended to be disposed of after single use. The thread provides extended temporary wound support, until the wound sufficiently heals to withstand normal stress, and is subsequently absorbed by hydrolysis. This is a single-use device.	D
88	Blanket/pad infant phototherapy unit	A device designed to emit a blue light in the visible wavelength of around 425-475 nm to treat neonatal jaundice (or hyperbilirubinemia). It consists of a fibreoptic-light source that connects through a flexible fibreoptic cable to a transparent blanket-like wrap or pad which emits the light and covers or encloses the neonate's body. Exposure to this device will alter the bilirubin through photo oxidation and configurational and structural isomerization allowing the body function to dispose of it naturally. This device can be suitable for home-use.	B

89	Flotation therapy bed, neonatal	A fixed (non-adjustable) device designed with a mattress or cushions containing air, water, gel, or other appropriate material used for the continuous care of newborns, and sick and/or premature babies. It has a size to suit such patients and provide environmental conditions (e.g., softness, illumination levels) appropriate for a neonate, as well as good working conditions for the healthcare staff; the bed is frequently mounted on wheels and may include or permit attachments for/to a baby warmer.	B
90	Mobile steam washer/disinfector	A mobile, mains electricity (AC-powered) unit designed for the cleaning and high-level disinfection of a range of medical devices (e.g., operating tables, operating lights, neonatal incubators, medical beds, chirurgical instruments) using steam. It includes an electronically controlled boiler unit, for steam generation; hosing, for transfer of the steam; and a hand-held steam application device, typically including accessories (e.g., brush, nozzle, mop), in order to effectively direct steam onto the medical device being disinfected.	C
91	Otoacoustic emission system, battery-powered	An assembly of battery-powered devices designed to record and analyse the faint sounds hair cells in the inner ear emit [otoacoustic emission (OAE)] in response to a stimulus (e.g., click, tone burst, pure-tone signals) to test for a deficiency of function in the ear during diagnostic evaluation and/or neonatal screening. It typically consists of a portable programmable unit, an OAE probe, and eartips. The stimulus signal is emitted via the probe inserted into the ear canal and the response is recorded via a microphone in the probe; OAEs are absent/reduced in patients with hearing loss. The system may be combined with other audiological devices (e.g., tympanometer, ABR device).	B
92	Otoacoustic emission system, line-powered	An assembly of mains electricity (AC-powered) devices designed to record and analyse the faint sounds hair cells in the inner ear emit [otoacoustic emission (OAE)] in response to a stimulus (e.g., click, tone burst, pure-tone signals) to test for a deficiency of function in the ear during diagnostic evaluation and/or neonatal screening. It typically consists of a programmable unit, an OAE probe, and eartips. The stimulus signal is emitted via the probe inserted into the ear canal and the response is recorded via a microphone in the probe; OAEs are absent/reduced in patients with hearing loss. The system may be combined with other audiological devices (e.g., tympanometer, ABR device).	B

93	Overhead infant phototherapy unit	A mains electricity (AC-powered) device designed to emit a blue light in the visible wavelength of around 425-475 nm to treat neonatal jaundice (hyperbilirubinemia). It consists of an overhead lamp consisting of several, daylight, cool white, blue, or special blue fluorescent light tubes / LEDs and a Plexiglas shield placed between the phototherapy lights and the newborn to filter out ultraviolet (UV) radiation. Exposure to this device will alter the bilirubin through photo-oxidation, and configurational and structural isomerization, allowing the body to dispose of it naturally. It will typically have a built-in timer, but some may have a separate timer unit connected.	B
94	Phototherapy eye protector, reusable	A device worn to cover and protect the eyes of a patient or user from potentially harmful rays [e.g., ultraviolet (UV)] to which parts, or all, of their body is intentionally exposed during light therapy treatment. It will typically be designed as goggles, special spectacles, or a mechanical mask-like shield with properties to block or inhibit the transmission of rays to the eyes. It will come in a variety of sizes, e.g., premature infant, neonatal, child, and adult. This is a reusable device.	A
95	Phototherapy eye protector, single-use	A device worn to cover and protect the eyes of a patient from potentially harmful rays [e.g., ultraviolet (UV)] to which their body is intentionally exposed during light therapy treatment. It will typically be designed as a mechanical mask-like shield with properties to block or inhibit the transmission of rays to the eyes. It will typically be made of soft materials in a variety of sizes, e.g., premature infant, neonatal and affix to the head using bands, hooks, Velcro fasteners, and/or adhesive fasteners. This is a single-use device.	A
96	Respiratory gas heating wire, infant	A non-sterile device intended to be integrated within a ventilator breathing circuit and used in conjunction with a heated respiratory humidifier (from which it draws its power) to maintain the temperature of inspiratory gases during ventilation of an infant/neonate. It typically consists of a compact heating unit and a length of heated wire which is integrated within the lumen of a neonatal/paediatric breathing circuit tube. This is a reusable device.	C
97	Stationary pneumatic high-frequency ventilator respiration monitor	A mains electricity (AC-powered) device intended to continuously measure and display respiratory variables associated with the operation of a stationary pneumatic high-frequency ventilator. Measurements include proximal airway pressure, high-frequency percussive rates, mean airway pressures and inspiratory and expiratory times. It is typically equipped with audible and/or visual alarms that are triggered when respiratory parameters drop below or exceed pre-set limits, and connectors for attachment to the ventilator. It may be used for neonatal, paediatric, and adult patients.	C

98	Syringe pump	A mains electricity (AC-powered) device designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution (e.g., 0.1 ml/hr), it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia. It will typically have internal batteries that allow the device to operate for a short period of time when no line power is available (e.g., during transport or a power outage).	C
99	Thoracic electrical impedance segmentography system	An assembly of devices designed to perform thoracic bio-impedance measurements to continuously record the distribution of air across 4 quadrants of the lungs, commonly of a neonatal/infant patient. It consists of a mobile support/trolley, a mains electricity (AC-powered) central unit with a display, and may include the appropriate patient electrodes. It is intended to detect changes in lung ventilation at a regional level, to assist in the diagnosis of lung conditions (e.g., atelectasis, pneumothorax, misplacement of endotracheal tube, effects of surfactant administration).	B
100	Thoracic electrical impedance segmentography system electrode array	A non-sterile, noninvasive component of a thoracic electrical impedance segmentography system intended to be attached to the skin surface of a neonatal/infant patient, to transmit electrical signals back to the system, for the continuous recording of the distribution of air across 4 quadrants of the lungs to assess a variety of pulmonary conditions/treatments (e.g., atelectasis, pneumothorax, endotracheal tube misplacement, effects of surfactant administration). It is a dedicated configuration of multiple electrodes. This is a single-use device.	B
101	Transcutaneous intracranial pressure sensor	A non-sterile electronic device exclusively intended for noninvasive measurement of intracranial pressure in a neonatal patient. Sometimes referred to as a fontanometer, it typically consists of a sensor, designed to be topically applied to the fontanel, and a cable, intended to be connected to an appropriate monitor to allow readings to be displayed and/or recorded. It may include a distal balloon to allow pressure baselines to be set. This is a reusable device.	C
102	Wearable neonatal heart rate meter	An electrically-powered device designed to detect and display the heart rate of a neonate, typically within the first few hours after delivery. It consists of a display screen with sensor arms on each side, which are placed around the torso of the newborn. This is a reusable device.	B

103	Antimicrobial infant garment	A piece of clothing (e.g., baby grow) intended to be worn by an infant affected by an infectious or infection-susceptible skin condition (e.g., eczema, psoriasis, epidermolysis bullosa) to help manage the condition by reducing microbial proliferation through fabric. It is constructed of a material which can prevent/control microbial growth (e.g., silk treated with a silica–ammonium chloride compound). It is available in various sizes for daily use in the home or healthcare facility. This is a reusable device.	B
104	Birthing bath	A large bath intended to be filled with heated water for use before and/or during child birth. It may be used to deliver the baby under water and/or to provide a comfortable environment for the expecting mother prior to birth. The device may also include specific features such as connectors and diagnostic attachments.	A
105	Boiling water sterilizer	A mains electricity (AC-powered) device designed for total elimination and/or inactivation of microorganisms from medical/dental devices and related products using boiling water as the sterilizing agent. It typically consists of a container intended to be filled with water, in which devices are submerged, and an apparatus to boil the water for a specific period. The device is almost exclusively used in remote areas, at home (e.g., for baby bottle sterilization), and/or in emergency situations.	B
106	Newborn-infant bed	A bed designed for newborn babies. It is usually an open rectangular receptacle, and mounted on a wheeled framework (trolley). It is padded or lined with appropriate bedding and used mostly as the general-purpose or standard baby bed in birthing departments. A source of additional heating may be provided to the newborn.	A
107	Resuscitator face mask, reusable	A flexible, form-shaped device that is placed over a patient's nose and mouth to direct ambient air, or medical oxygen (O2) and air, from a resuscitator to the upper airway and lungs. It is typically made of non-conductive sterilizable materials (e.g., silicone) that will create a gastight seal against the face. It will typically include a 15 mm and/or 22 mm connector and is available in a range of sizes (baby to adult). It will be directly attached to the resuscitator and held in place on the patient's face by the operator. This device is intended for use with a breathing resuscitator but may be used for the delivery of anaesthesia gases. This is a reusable device.	B

108	Resuscitator face mask, single-use	A non-sterile, flexible, form-shaped device that is placed over a patient's nose and mouth to direct ambient air, or medical oxygen (O2) and air, from a resuscitator to the upper airway and lungs. It is typically made of non-conductive sterilizable materials (e.g., silicone) that will create a gastight seal against the face. It will typically include a 15 mm and/or 22 mm connector and is available in a range of sizes (baby to adult). It will be directly attached to the resuscitator and held in place on the patient's face by the operator. This device is intended for use with a breathing resuscitator but may be used for the delivery of anaesthesia gases. This is a single-use device.	B
109	Warming infant bed, adjustable	A mains electricity (AC-powered) bed specifically designed for a newborn, sick, or premature baby that requires additional heating provided by a heating pad system. It is typically ergonomically designed for the attending/nursing staff or parents and the motorized mechanism is used to electrically adjust the height and possibly tilt the bed to provide better access to the baby. It may be equipped with features such as shelves, drawers, a canopy, and is typically used in the maternity department.	C
110	Warming infant bed, non-adjustable	A non-adjustable bed (has a fixed height and mattress platform) specifically designed for a newborn, sick, or premature baby that requires additional heating provided by a heating pad system. It is typically ergonomically designed to provide good access to the baby by the attending/nursing staff or parents. It may be equipped with features such as shelves, drawers, a canopy, and is typically used in the maternity department.	C
111	Bedrail pad	A device which is formed as a flat or contoured fitted cushion made of soft, non-irritating materials designed to protect the patient from coming into contact with the bedrails and inadvertently hurting or injuring themselves. It will be mainly used for patients that have little self-control, infants and very young children. This is a reusable device.	A
112	Blanket/pad infant phototherapy unit tester	A portable device intended to be used in conjunction with a light meter to test a blanket/pad infant phototherapy unit. The phototherapy unit is typically positioned over specific areas of the test device at set distances to provide a measurement of light, such as average light output. It typically consists of a plastic stencil-like shape designed so the radiometer may fit at a number of positions. It is intended to be used by a healthcare professional in a clinical setting.	B

113	Blood transfusion set, exchange	A sterile, intravascular administration set used to remove a diseased infant's blood and replace it with fresh donor blood or plasma. The device typically includes a needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, a stopcock, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an intravenous (IV) bag or other infusion fluid container. This is a single-use device.	B
114	Blue light radiometer	An instrument designed to measure the radiant flux (radiant power) in the spectral range of 400 to 500 nm (i.e., blue) during bilirubinemia treatment for newborns and infants. It typically includes a pre-filter intended to remove wavelengths of light not in the 400-500 nm range (e.g., infrared light); a primary detector consisting of a temperature-stabilized, solid-state [e.g., selenium (Se) or indium-gallium-arsenide] device used to detect radiation; electronic circuits including an amplifier and a electric meter; a power source (e.g., a battery); and a display showing the results either in analogue or digital format.	B
115	Cardiac septostomy catheter, balloon	A flexible tube with an inflatable balloon designed to create or enlarge the atrial septal defect found in the hearts of infants with congenital cardiac malformations. This allows interatrial blood mixing in infants with transposition of the great vessels. This is a single-use device.	C
116	Cardiac septostomy catheter, blade	A flexible tube with a collapsible blade at the distal end that, once in situ, can be raised to an acute angle by the surgeon operating an actuation lever at the proximal end for a blade atrial septostomy (BAS) procedure. It is used to enlarge the interatrial opening in cases of mitral atresia (a septal defect found in the hearts of infants) or unsuccessful or insufficient balloon atrial septostomy. This procedure allows interatrial blood mixing in infants with congenital cardiac malformations. It is typically made of plastic and high-grade stainless steel materials. This is a single-use device.	C
117	Conventional infant incubator	A mains electricity (AC-powered) unit designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature. It typically consists of a clear removable plastic hood with a mattress. It typically includes a means to warm the infant such as providing heated air (either by natural flow or forced) or through a warm water mattress; temperature controls that work automatically either by measuring the air temperature or through a temperature sensor attached to the infant skin; and humidity controls. The device is intended to remain in a hospital ward.	C

118	Cranial orthosis	A custom-made helmet-like device intended to be worn on the head of an infant with an abnormal head shape (e.g., due to plagiocephaly, brachycephaly, scaphocephaly), or after craniosynostosis repair surgery, to apply pressure to the cranium and improve cranial symmetry/shape during growth over a period of months. It is made of durable materials (e.g., plastic, solid foam) and is designed with patient-specific characteristics (e.g., size, shape) based on head measurements (e.g., clinical pictures, 3-D scans, casts). It is typically worn during daily activities and sleep. This is a single-patient device that can be reapplied during the treatment period (reusable) before being discarded.	B
119	Home BPAP unit	A portable mains electricity (AC-powered) device, which may include rechargeable batteries, intended to assist noninvasive ventilation (i.e., without use of an artificial airway) using bi-level positive airway pressure (BPAP) during spontaneous respiration for adult/child (non-infant) patients affected by obstructive sleep apnoea (OSA), and/or to treat patients with conditions requiring respiratory assistance in the home [e.g., chronic obstructive pulmonary disease (COPD)]. It is a small desktop unit, which may include a built-in humidifier, intended to be used with a separate nose/mouth mask. The device is intended for use in the home but may also be used in healthcare facilities.	B
120	Multi-purpose saline solution	A sterile, water-based, salt solution (e.g., sodium chloride isotonic solution) intended for alternative use in multiple applications including inhalation therapy, moisturizing and washing/irrigation of the eyes, nose and ears, and wound cleansing; it is not dedicated to a specific application or part of the anatomy. It is typically available in a squeeze bottle for self-administration or application to infants for preventive or symptomatic care. It is normally available (non-prescription) over-the-counter (OTC) for home use. After application, this device cannot be reused.	B
121	Nappy changing table, portable	A raised device consisting of a platform with a full-body length top surface (this may be slightly concave and padded to prevent the patient easily rolling off) mounted on a foldable frame with legs designed to support an infant, child or an adult during nappy (diaper) changing. The device is used primarily for a patient with a disability who is incontinent and requires regular changing of their nappies. It is designed to be portable for transport to different locations.	A

122	Nasal aspirator, electric	A portable, hand-held, battery-powered suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing. It consists of a handgrip that contains the batteries, a small electric pump that creates the suction, and typically has a silicone nozzle attached to a detachable, washable, collection cup at the distal end. It is designed for domestic use and is typically applied superficially the nasal opening (i.e., not inserted into the nasal cavity). This is a reusable device.	A
123	Open infant incubator	A mains electricity (AC-powered) unit that functions similar to a standard infant incubator but is open, having low side walls and no top enclosure, giving instant access to the infant. Such infants are not premature but suffer from disorders where intensive care is required. This device is equipped with overhead heating lamp(s), oxygen therapy flowmeter, gas mixer, suction system, facilities for infusion pumps, and other equipment. The main difference between this device and a closed infant incubator is the inability of this device to regulate the oxygen environment surrounding the occupant.	C
124	Oral medicine dropper	A device designed for aspirating a small volume of liquid medicine so that it can be dispensed in single drops into a patient's mouth, typically an infant or small child. It is typically designed as a hollow tube, open at both ends, with an aspiration bulb attached to the proximal end and a narrow opening at the distal end. It is usually made of glass or plastic with a rubber teat. This is a reusable device.	A
125	Oxygen breath analyser	A mains electricity (AC-powered) laboratory instrument designed for intermittent/periodic measurements of oxygen (O2) content in a breath and/or respiratory gas specimen. It usually requires manual aspiration of a quantity of gas into a sampling chamber and may operate according to one of several basic principles (e.g., paramagnetism, polarography). The device is used in pulmonary function tests and for measurements in critically ill patients, such as infants in incubators and patients breathing air with supplemental oxygen.	C
126	Oxygen terminal unit	A device that is a component of a medical gas pipeline system or a medical gas/vacuum pipeline system that has a gas-specific outlet connection for oxygen (O2). It is designed to be mounted to wall-mounted medical supply units, utility supply systems (ceiling pendants), or directly to a wall, and functions as the outlet assembly of a gas pipeline system to which the operator can connect and disconnect a device, typically anaesthesia systems, ventilators, respiratory devices, infant incubators, and other devices that require O2 to function as intended. On disconnection of the medical device from the outlet, it will self seal the gas pipeline system preventing gas leakage to the environment.	A

127	Pulmonary function analysis system, paediatric	A computerized instrument designed to assess lung volume, flow, and mechanical parameters (including airway compliance and resistance) in young children and infants. It is different from an adult version in absolute dimensions and in the special procedures required for adaption to the pediatric patient (e.g., use of a small constant-volume chamber in which the infant reclines for plethysmography, use of a pressure jacket to obtain forced exhalation); also, parameters that require subject cooperation (e.g., vital capacity, forced expiratory volume) can't be determined. The device is used for pulmonary function testing in diagnostic studies and for evaluation of diseases and chest deformities.	B
128	Reactive-gel heating pad	An underlay intended to produce heat through chemical reaction typically used to warm and/or maintain the body temperature of neonates or infants. It is typically designed with a soft outer casing (e.g., a soft plastic) that contains a chemically-reactive-gel activated by the user (e.g., by breaking its inner enclosure) to provide a heat of approximately normal body temperature (e.g., 38° Celsius) for a limited period. This device is typically used to maintain the body temperature of infant patients during transportation and may be x-ray translucent and magnetic resonance imaging (MRI) compatible. This is a single-use device.	B
129	Respiratory apnoea monitoring system	An assembly of devices designed to detect the cessation of breathing (apnoea) in infants and adults who are at risk of respiratory failure to alert a parent or attendant of the life-threatening episode(s). It alarms primarily upon the cessation of breathing timed from the last detected breath, and may also include indirect methods of apnoea detection such as monitoring of heart rate and other physiological parameters associated with respiration. It may print-out this data. It will typically include a mains electricity (AC-powered) monitoring unit with software, patient leads, and possibly a recorder to record, display, or print data on a patient's breathing condition.	C
130	Rocking infant bed, electric	A mains electricity (AC-powered) bed designed to provide a motorized rocking movement for newborn babies to soothe the infant. The motorized mechanism is control-adjustable to provide variable degrees of movement and speed.	B
131	Skin transilluminator, battery-powered	A hand-held, battery-powered device with a built-in light source, usually together with a lens, intended to be used to illuminate the skin and soft tissues, rendering them translucent for examination. It is typically used to examine subcutaneous and scrotal tissue/contents for lesions, and veins (e.g., on the scalp of an infant) for anatomical abnormalities. This device may also be known as a diaphanoscope, a phaneroscope or a light scanner.	C

132	Skin transilluminator, line-powered	A hand-held, mains electricity (AC-powered) device with a built-in light source, usually together with a lens, intended to be used to illuminate the skin and soft tissues, rendering them translucent for examination. It is typically used to examine subcutaneous and scrotal tissue/contents for lesions, and veins (e.g., on the scalp of an infant) for anatomical abnormalities. It can use varying forms of light depending upon the specific application. This device may also be known as a diaphanoscope, a phaneroscope or a light scanner.	C
133	Teething device, fluid-filled	A circular or cylindrical device filled with fluid (e.g., water) intended to be bitten by a patient (infant or adult) to soothe gums during the teething process. This is a reusable device.	B
134	Teething device, non-fluid-filled	A circular or cylindrical device free of fluid and intended to be bitten by a patient (infant or adult) to soothe gums during the teething process. This is a reusable device.	A
135	Transport infant incubator	An electrically-powered unit designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature; it is typically on wheels and also designed for transporting infants either outside or within the healthcare facility. It typically consists of a clear removable plastic hood with a mattress and operates using mains electricity (AC-powered) when not in use for transportation. During transport, it is connected to an ambulance electrical outlet or is battery-powered from a battery pack.	C
136	Visual-reinforcement-audiometry reward system	An assembly of mains electricity (AC-powered) devices intended to be used in conjunction with an audiometer to reward an infant/child during instrumentation conditioned reflex audiometry/play audiometry. It includes hardware (e.g., monitor, lights) intended to give the child a visual reward, and dedicated operating software; it may include additional controls (e.g., foot-switch) and toys. It is intended to be operated by the healthcare professional to build the conditioned response during auditory testing.	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (145) **Date:** 23 AUG 2021

Subject: Classification of medical device pertaining to Urology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants who intend to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File No. 29/Misc./03/2020-DC (145)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Urology

S. No.	Device Name	Intended Use	Risk Class
1	Bare-metal urethral stent, short-term	A sterile non-bioabsorbable tubular device intended to be placed short-term (<= 30 days) in the urethra to facilitate urethral patency and an unimpeded flow of urine from the bladder; it is typically used to relieve lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).	C
2	Biliary/urinary stone retrieval basket	A flexible manual instrument designed to remove biliary and/or urinary stones (gallbladder and/or renal calculi) from the body during an endoscopic procedure.	B
3	Bladder neck spreader	A manual gastroenterology-urology surgical instrument with specially designed moveable blades intended to be used to separate and spread the bladder neck. This is a reusable device.	A
4	Bladder-emptying vibratory stimulator	A battery-powered, hand-held device intended to be used in the home or healthcare facility by a patient to help initiate urination and facilitate complete bladder emptying through application of small mechanical vibrations to the lower abdomen to promote urethral sphincter relaxation.	B
5	Closed-ended wearable urine collection bag, non-sterile	A non-sterile flexible plastic pouch designed to connect to a urinary catheter and to be strapped to the leg of a patient to collect discharged urine; it is not designed with an opening for urine drainage.	A
6	Closed-ended wearable urine collection bag, sterile	A sterile flexible plastic pouch designed to connect to a urinary catheter and to be strapped to the leg of a patient to collect discharged urine; it is not designed with an opening for urine drainage.	A
7	Cystometer	A device used to examine the bladder, providing measurement data concerning pressure and volume. This data will be used for diagnostic evaluation of the neuromuscular mechanisms of the bladder.	B
8	Cystometer probe, ultrasonic	A device that emits ultrasound energy generated by a cystometer in order to study bladder function by measuring bladder capacity, sensation, pressure, and residual urine.	B
9	Cystoscopic electrode	A sterile electrical conductor intended to be placed in contact with the bladder to stimulate it and/or record its electrical activity for diagnostic examination.	B

10	Diaphragm wearable urinal	A non-sterile urine drainage device designed for men with incontinence consisting of a front piece with a scrotal support and a leak-proof, flexible diaphragm through which the penis passes into a closed cone-shaped tube connected to a leg bag into which the urine is collected.	A
11	Draping incontinence liner	A non-sterile padded sheet intended to cover and protect a device/piece of furniture (e.g., wheelchair, bed, sofa) occupied by an incontinent person by catching and retaining urine.	A
12	Drip wearable urinal	A non-sterile urine drainage device designed for men to contain a moderate leakage consisting of a front piece with an integrated tubular sheath that fits fully over the penis and into which dribbling urine is collected.	A
13	Electrohydraulic lithotripsy system	An assembly of devices that uses plasma-induced shock waves for the intracorporeal fragmentation of stones (calculi) found in the kidney, ureter, and bladder.	B
14	Electrohydraulic/pneumatic lithotripsy system probe, urinary, single-use	A sterile, slender, rod-like device intended to be used as part of an intracorporeal lithotripsy system to transmit shock waves from electrohydraulic or pneumatic sources directly to a calculus in the urinary tract (i.e., kidneys, ureters, and bladder), providing high-speed fragmentation of the calculus in situ.	B
15	Electromechanical lithotripsy system, extracorporeal	An assembly of devices that non-invasively disintegrates stones (i.e., calculi) by sending focused shock waves from outside the body produced by an electromechanical generator.	B
16	Electromechanical lithotripsy system, intracorporeal	An assembly of devices designed to create shock waves through electromechanical action for the intracorporeal fragmentation of calculi (stones) in the urinary tract (i.e., kidney, ureter and bladder); the resulting debris may be actively removed or passed out by natural means at a later date.	B
17	Female wearable urinal, reusable	A non-sterile, urine drainage device designed for women that typically consists of a flexible tube attached to a collector that is specially formed to securely fit around the female genitals to provide a route to channel urine, via a tube, into a collection bag.	A
18	Fibreoptic ureteral catheter, reusable	A flexible tube containing a fibreoptic bundle that emits light throughout its length, intended to be inserted into the ureter for illumination to enable the path of the ureter to be seen. It also includes a plug for connection to a fibreoptic light source and a port for irrigation at its proximal end.	B
19	Filiform urethral bougie	An extremely thin, wire-like, manual surgical instrument designed for traversing and exploring urethral strictures and/or dilating the urethra, introduced directly or through an appropriately-threaded urethral catheter.	B

20	Flexible endoscopic stone-retrieval forceps, reusable	A flexible manual device intended to be inserted through the working channel of a compatible flexible endoscope to grasp and remove stones (e.g., calculi from the urinary tract) or foreign bodies during an endoscopic procedure.	B
21	Flexible fibreoptic cystonephroscope	An endoscope with a flexible inserted portion intended for the visual examination/treatment of the bladder, the urethra (including the prostate region), and the kidneys.	B
22	Flexible fibreoptic cystoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urinary tract.	B
23	Flexible fibreoptic cystourethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urethra, including the prostate region.	B
24	Flexible fibreoptic nephroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the kidney. It is inserted percutaneously into the renal pelvis during nephroscopy.	B
25	Flexible fibreoptic ureterorenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis.	B
26	Flexible fibreoptic ureteroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter (the upper urinary tract that connects the kidney to the bladder).	B
27	Flexible fibreoptic urethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the urethra (the muscular tube that leaves the urinary bladder for the excretion of urine).	B
28	Flexible ureteral sheath/fibreoptic telescope	A sterile device assembly intended to function as a flexible endoscope for the visual examination and treatment of body cavities/organs that can be accessed via the ureter for cystoscopic, nephroscopic, laparoscopic, and ureteroscopic procedures.	B
29	Flexible video cystonephroscope	An endoscope with a flexible inserted portion intended for the visual examination/treatment of the bladder, urethra (including prostate region), and kidneys.	B
30	Flexible video cystoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urinary tract by introduction through the urethra.	B
31	Flexible video cystourethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urethra, including the prostate region.	B
32	Flexible video nephroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the kidney.	B

33	Flexible video ureterorenoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis.	B
34	Flexible video ureteroscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the ureter (the upper urinary tract that connects the kidney to the bladder).	B
35	Flexible video urethroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the urethra (the muscular tube that leaves the urinary bladder for the excretion of urine).	B
36	General-purpose ureteral catheter	A flexible tube designed for introduction into the ureters through a cystoscope or nephroscope.	B
37	Hand pneumatic lithotripsy system, urinary	An assembly of devices, held by the operator, that uses pneumatically-created ballistic shock waves for the intracorporeal fragmentation of stones (calculi) in the urinary tract (i.e., kidneys, ureters, and bladder) for their removal.	B
38	Hand-held urinal, female	A portable, hand-held container/set, typically made of plastic, intended to be directly urinated into by a female (typically bed-bound) patient for excretory purposes.	A
39	Hand-held urinal, male, reusable	A portable, hand-held container intended to be directly urinated into by a male (typically bed-bound) patient for excretory purposes.	A
40	Hepatic function analysis system	An assembly of mains electricity (AC-powered) devices intended to aid in the quantitative assessment of liver function by the in vivo measurement of the plasma concentration and clearance of a tracer substance [e.g., indocyanine green (ICG)] in the peripheral vasculature following intravenous injection.	B
41	Home faecal specimen collection kit	A collection of non-sterile devices and materials intended to be used by a layperson to collect and mail a faecal (stool) sample to a clinical laboratory for diagnostic testing or screening purposes (e.g., occult blood, cytology).	A
42	Hydraulic male urinary incontinence treatment system	An assembly of implantable devices intended to treat male urinary incontinence by applying pressure to partially/fully occlude the bladder neck and/or urethra, typically after radical prostatectomy or transurethral resection of the prostate.	C
43	Hydraulic male urinary incontinence treatment system port	An implantable component of a hydraulic male urinary incontinence treatment system intended to provide access to the system's inflatable pad (e.g., cushion, balloon), for the intra- and/or postoperative introduction/removal of fluid (e.g., saline).	C

44	Hydraulic male urinary incontinence treatment system tubing	An implantable length of tube that functions as a component of a hydraulic male urinary incontinence treatment system and intended to provide connection between the system's inflatable pad (e.g., cushion, balloon) and the system's port, for the intra- and/or postoperative introduction/removal of fluid (e.g., saline); it is typically made of silicone and metal.	C
45	Hydraulic male urinary incontinence treatment system tubing plug	An implantable component of a hydraulic male urinary incontinence treatment system intended to seal the system's tubing to prevent spillage/leakage of its contents when introduction/removal of fluid to/from the system's pad (e.g., cushion, balloon) is not needed; it is typically made of metal.	C
46	Incontinence device suspender	A device used by a person with a disability to secure a body-worn incontinence device [e.g., a nappy (diaper) or a pad] in a stable and safe position.	A
47	Incontinence penis clamp, reusable	A male urinary incontinence device designed to gently compress the penis, either the proximal shaft or the glans penis, to occlude the urethra and prevent involuntary urination/dribbling for men who are incontinent of the bladder.	A
48	Incontinence sensor/alarm	A electrically-powered electronic device intended to provide an audible, visible and/or tactile signal to alert the patient or a caregiver when a small quantity of urine and/or faeces incontinently released is detected by a sensing mechanism (e.g., a sensor pad or detector).	B
49	Inflatable penile prosthesis	An inflatable/deflatable sterile device designed of several interconnected components intended to be surgically implanted in a patient with erectile dysfunction (ED) [commonly known as impotence] in order to achieve selective penile tumescence and rigidity adequate for vaginal intercourse	C
50	Intermittent urethral catheterization kit, non-sterile	A collection of non-sterile devices that includes a urological catheter (with or without a urine drainage bag), a cap, and other related accessories intended for self-urinary catheterization.	B
51	Intermittent urethral catheterization kit, sterile	A collection of sterile devices that includes a urological catheter (with or without a urine drainage bag), a cap, and other related accessories intended for self-urinary catheterization.	B
52	Intermittent urethral drainage catheter, antimicrobial	A sterile, flexible or rigid, tube designed to be repeatedly inserted through the urethra, typically by the user (i.e., self-applied), to the urinary bladder to provide short-term, episodic urine drainage (removed after each void), typically for an individual who is physiologically incapable of voiding.	B

53	Intermittent urethral drainage catheter, non-sterile	A non-sterile, flexible or rigid, tube designed to be repeatedly inserted through the urethra, typically by the user (i.e., self-applied), to the urinary bladder to provide short-term, episodic urine drainage (removed after each void), typically for an individual who is physiologically incapable of voiding.	B
54	Intermittent urethral drainage catheter, sterile	A sterile, flexible or rigid, tube designed to be repeatedly inserted through the urethra, typically by the user (i.e., self-applied), to the urinary bladder to provide short-term, episodic urine drainage (removed after each void), typically for an individual who is physiologically incapable of voiding.	B
55	Intracorporeal lithotripsy suction system	An assembly of devices designed for use with an intracorporeal lithotripsy system to evacuate, by suction, the irrigation fluid-containing fragments of urinary calculi from the kidneys, ureters, and bladder during lithotripsy.	B
56	Intraurethral valve/pump	A sterile, non-powered device intended to be inserted into the female urethra to facilitate urine voiding in patients with incomplete bladder emptying due to impaired detrusor contractility (IDC) of neurologic origin.	B
57	Laser lithotripsy fibre/suction guide	A sterile device intended to be inserted through the working channel of a rigid nephroscope during laser lithotripsy to function as a channel for insertion of the laser fibre of a laser beam guide (e.g., of a general/multiple surgical laser system), and for removal of debris (e.g., fluid, calculi fragments) when connected to a vacuum source.	C
58	Laser lithotripsy system	An assembly of devices consisting of a specialized ureteroscope, a laser resistant catheter, and a dedicated laser designed for the intracorporeal disintegration of ureteral stones (calculi).	C
59	Lithotrite	A hand-held manual surgical instrument designed for the mechanical crushing of renal stones (calculi) in the urinary tract and/or bladder	B
60	Male urinary outflow analysis system	A mains electricity (AC-powered) assembly of devices intended to be used to measure urine flow rate and to estimate iso-volumetric bladder pressure in men with the use of an inflatable penile cuff. It typically consists of a dedicated computer and application software, an automatic cuff inflation/deflation unit, a single-use penile cuff, and a load-measuring cell/stand.	B
61	Male urinary outflow analysis system cuff	A non-sterile inflatable cuff that is a component of a male urinary outflow analysis system.	B
62	Manometric catheter sheath	A non-sterile, synthetic polymer sleeve intended to cover/protect and prevent contamination of a manometric catheter (including barostat catheter).	B

63	Microwave hyperthermia system catheter, prostatic-ablation, reusable	A thin rod intended to be used as part of a hyperthermia system to treat disorders of the prostate [e.g., cancer, benign prostatic hyperplasia (BPH), prostatitis] through the local application of heat from microwaves.	C
64	Penile extracorporeal shock wave therapy system	A mobile assembly of devices designed to provide spark-gap-generated, low-intensity, extracorporeal shock wave therapy to treat erectile dysfunction (ED) [impotence] to rehabilitate penile erection and rigidity adequate for intercourse.	B
65	Penile extracorporeal shock wave therapy system applicator	A hand-held device designed to transmit spark-gap-generated (electrohydraulic), low-intensity, shock waves from a penile extracorporeal shock wave therapy system generator to the skin of the penile shaft and the penile crura to treat erectile dysfunction (ED) [impotence] to rehabilitate penile erection and rigidity adequate for intercourse.	B
66	Penis wearable urinal	A non-sterile, externally-worn, urine drainage device intended to be worn over the penis of an incontinent male patient to channel urine, via a tube, into a collection bag. It consists of a urinary incontinence penis attachment (e.g., sheath or adhesive port), tubing, and a wearable urine collection bag.	B
67	Penis/scrotum wearable urinal	A non-sterile urine drainage device designed for men with incontinence and a retracted penis that includes a front piece (a shaped cone) intended to contain both the penis and the scrotum to form a leak-proof seal around the male genitals.	B
68	Perineal orifice incontinence-control electrical stimulation system, remote control	An assembly of battery-powered, remote-controlled devices designed for intravaginal pelvic floor exercise to treat urinary incontinence and other pelvic problems in women (e.g., pelvic pain and sexual dysfunction) through the application of electrical stimuli to the muscles of the pelvic floor.	C
69	Piezoelectric lithotripsy system	An assembly of devices that non-invasively disintegrates stones (i.e., calculi) by sending focused shock waves from outside the body produced by a piezoelectric generator.	C
70	Pyeloscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the renal pelvis and major or minor calyces.	B
71	Rigid cystoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the bladder and the urinary tract.	B
72	Rigid cystourethroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the bladder and the urethra, including the prostate region.	B
73	Rigid nephroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the kidney.	B

74	Rigid ureterorenoscope	An endoscope with a rigid or semi-rigid inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis; some types may have a flexible tip at the distal end of the inserted portion.	B
75	Rigid ureteroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the ureter, (the upper urinary tract that connects the kidney to the bladder).	B
76	Rigid urethroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the urethra (the muscular tube that leaves the urinary bladder for the excretion of urine).	B
77	Rigid video ureterorenoscope	A sterile endoscope with a rigid or semi-rigid inserted portion intended for the visual examination and treatment of the ureter and the renal pelvis; some types may have a flexible tip at the distal end of the inserted portion.	B
78	Spark-gap lithotripsy system	An assembly of devices that non-invasively disintegrates stones (i.e., calculi) by sending focused shock waves from outside the body produced by a spark-gap generator.	B
79	Suprapubic needle, surgical, reusable	A hand-held manual surgical instrument designed with a sharp pyramidal or conical point at the distal end to percutaneously puncture the lower abdominal wall to provide suprapubic access for surgical repair, typically to position a sling used in the treatment of female stress urinary incontinence (SUI) associated with bladder prolapse.	B
80	Temperature-monitoring indwelling urethral drainage catheter	A sterile, flexible tube with an inflatable balloon on its distal tip for retention in the urinary bladder, after its insertion through the urethra, where it functions as a long-term indwelling device for continuous urinary drainage and simultaneous monitoring of core body temperature through its integral temperature sensor, typically during or after surgery or in the presence of obstruction or paralysis.	B
81	Transobturator needle, reusable	A hand-held manual surgical instrument with a sharp pyramidal or conical point used to create a percutaneous puncture using the transobturator approach (i.e., the insertion points overlie the obturator space in the genitofemoral crease lateral to the vagina), for the surgical positioning of a sling used in the treatment of stress urinary incontinence (SUI), which may be associated with a prolapse.	B
82	Transvaginal needle, surgical	A hand-held manual surgical instrument with a sharp pyramidal or conical point designed to create a puncture in the vaginal wall for the surgical positioning of a sling typically used in the treatment of stress urinary incontinence (SUI) associated with bladder prolapse.	B

83	Ultrasonic lithotripsy system	An assembly of devices designed to use ultrasonic (US) shock waves for the intracorporeal fragmentation of stones (calculi) found in the kidney, ureter, and bladder.	B
84	Ureteral patency kit	A collection of devices intended to assist treatment of a blocked ureter and to help maintain ureteral patency through natural orifice or percutaneous access.	B
85	Urethral drainage catheter punch	A hand-held manual instrument designed for cutting a small hole (e.g., 0.3 mm diameter) into the distal end of a closed Foley catheter (usually 14.0 French or larger) to form a "Council tip Foley catheter", allowing it to be placed over a guidewire or ureteral catheter.	B
86	Urethral/suprapubic catheter valve-connector	A small, sterile valve intended to be connected to a urethral and/or suprapubic catheter to allow intermittent bladder drainage/filling (as an alternative to continuous drainage).	A
87	Urinary-incontinence vaginal insert, reusable	A non-sterile, device intended to be inserted into the vagina in order to relieve mixed or stress urinary incontinence in an adult female by providing urethral support when pressure is transferred from the abdomen to the pelvic floor area (e.g. upon coughing, laughing, sneezing, exertion).	A
88	Urodynamic measurement system	An assembly of devices used for advanced diagnosis/study of the bladder. It is used to identify the cause of abnormal voiding, including incontinence and is useful for the diagnosis of, e.g., neurogenic bladder diseases, stress incontinence, urinary path obstruction or spastic sphincters.	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (186) Date: 13 SEP 2021

Subject: Classification of Medical Device pertaining to Personal Protective Equipment under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File No. 29/Misc./03/2020-DC (186)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Personal Protective Equipment

S. No.	Medical Device Name	Intended Use	Risk Class
1	Garment, Protective for Incontinence	Intended to protect an incontinent patient's garment from the patient's excreta.	A
2	Biosanitizer for Medical devices	Intended for surface disinfection of medical devices, non porous hard-surfaces, medical-equipment, units, as well as in-depth cleaning of small surfaces.	B
3	Face shield	Intended to protect the wearer's entire face (or part of it) from hazards such as chemical splashes (in laboratories or in industry), or potentially infectious materials (in medical and laboratory environments).	A
4	Latex surgical glove	Natural rubber based glove intended to protect the patient and wearer from cross infection when used in medical or dental surgery.	B
5	Non-latex surgical glove	Synthetic material glove intended to protect the patient and wearer from cross infection when used in medical or dental surgery.	B
6	Radiation protection gloves	A personal protection device that completely protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.	A
7	Partial hand radiation protector	A flat pad with straps or partial gloves that protect part of hands and fingers from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.	A
8	Radiation protection apron	A standard length or half-length apron to protect the patient, the operator, and other personnel from radiation exposure during a medical or dental procedure. Some have a fixed or removable collar to protect the neck and thyroid.	A
9	Radiation protection mitten	A personal protection device that protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures. The mittens are also called mitts, and protect the thumb and other fingers individually or together.	A

10	Radiation protection goggles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment.	A
11	Radiation face protector	A transparent or opaque personal protection device that protects the face and eyes of medical personnel and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment.	A
12	Operator radiation protection spectacles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment.The device comes in non-correction (non-prescription) glasses and visual acuity correction (prescription) glasses.	A
13	Gonadal radiation protector	A personal protection device that attenuates unnecessary radiation exposure in diagnostic, medical or dental procedures, and shields the gonad of the patient and the operator.	A
14	Radiation protection blanket	A personal protection device that protects specific body parts of the patient, operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment.	A
15	Radiation protection collar	A personal protection device that protects the neck or thyroid of the patient, the operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment.	A
16	Radiation protection cap	A personal protection device that protects the head of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical procedures for diagnosis and treatment.	A
17	Mobile radiation protection barrier	A stand-alone, movable barrier that protects the operator etc. from unnecessary exposure to radiation used for medical diagnosis, treatment and dental procedures.	A
18	Non-latex medical examination glove	Gloves made of synthetic materials, and used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery.	A
19	Latex medical examination glove	Natural rubber gloves used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery.	A
20	chemotherapy spill clean-up kit	Designed to safely clean and dispose of Chemotherapy drug spills.	A
21	Medical/Cadaver Body Bags	Intended for transporting a human corpse without any spread of biohazard/infectious agent.	A

22	Surgical gown (Sterile)	A sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	B
23	Surgical gown (Non-Sterile)	A non-sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	A
24	Isolation Gown) (Sterile)	A sterile garment made of natural and/or synthetic materials intended to be worn by healthcare providers or visitors to isolate themselves from patients to protect the themselves from a contagious agent which has infected the patient.	B
25	Isolation Gown (Non-Sterile)	A non-sterile garment made of natural and/or synthetic materials intended to be worn by healthcare providers or visitors to isolate themselves from patients to protect the themselves from a contagious agent which has infected the patient.	A
26	Patient Gown	A garment made of natural and/or synthetic materials (e.g., paper, cloth, plastic) intended to be worn by patients in a clinical setting (e.g., during hospitalization, during examination in a doctor's office). A patient gown is usually short-sleeved and may be closed by ties at the back/side of the garment.	A
27	Professional Examination Gown	A garment made of natural and/or synthetic materials intended to be worn by healthcare providers, sometimes over scrub suits, while examining patients. It can be fluid resistant or impervious to fluid. An examination gown is used during patient examination procedures to protect both the patient and staff from the transfer of contaminants such as microorganisms or body fluids.	A
28	Personal Protective Equipment	PPE kit used to acts as a barrier between infectious materials such as viral and bacterial contaminants and skin, mouth, nose, or eyes. It refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.	B
29	Surgical Helmet	Intended to protect healthcare workers from contaminants & debris on head.	A
30	Surgical Cap	Intended to protect face of patient & the operating room personnel from the transfer of micro-organisms, body fluids & particulate material.	A
31	Operating Room Shoes Cover	Intended to be worn by operating room personnel during surgical procedures to protect foot of both the surgical patient & the operating room personnel from transfer of micro-organisms, body fluids, and particulate material.	A

32	Surgical Drape & Drape Accessories	A surgical drape & drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial & other contamination.	B

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (178) **Date:** 13 SEP 2021

Subject: Classification of medical device pertaining to Pain Management under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classifiy the medical devices based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC(178)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Pain Management

Sr. No	Medical Device Name	Intended Use	Risk Class
1	Acupressure wristband	A device designed to be worn on the wrist(s) for the application of pressure to the Nei-kuan (P6) acupressure point, the area identified to help relieve the sensation of nausea.	A
2	Acupuncture electrical stimulation system	An assembly of devices used to apply electrical stimuli to acupuncture sites.	B
3	Acupuncture kit	A collection of instruments and supplies used to perform acupuncture procedures.	B
4	Acupuncture point detector	An electronic probe used to precisely locate an acupuncture point on a patient's body.	B
5	Analgesic spinal cord electrical stimulation system	An assembly of devices that applies an electrical stimulus to all or part of the spinal cord to relieve pain (analgesia).	C
6	Bite relief pad	A thin, plastic, horshoe-like wafer that is placed between the upper and lower sets of teeth and bitten down on, or chewed, to help relieve pain or discomfort after orthodontic treatment.	A
7	Cryogenic analgesia unit	A device designed to provide analgesia by applying extremely low temperatures to body tissues. It is used for postoperative and chronic intractable pain relief.	C
8	Ear microsystem needle	An instrument used in auriculotherapy to apply continuous pressure to stimulate meridian points.	A
9	Electric pad localized-body heating system	An assembly of devices designed for the transcutaneous application of heat to a localized body site to relieve musculoskeletal pain.	B
10	Endothermic cold therapy pack	A device intended to be applied with pressure to the body surface to provide cold therapy to help reduce fever, pain, and inflammation associated with joint/muscle/tissue injury and/or minor burns.	B
11	Foot bath	A device designed to be filled with water to provide therapeutic heat treatment specifically to the feet. This device is intended to relieve foot pain as well as headaches, coughs, and other cold symptoms.	A
12	Heat therapy gel	A non-sterile gelatinous compound in a container that is dispensed for application to the body surface to provide a warming effect for underlying tissues. It is intended to reduce/relieve pain, muscle tension, and to increase local circulation.(Not in direct contact with tissue)	A
13	Ice bag	Intended to alleviate pain and/or promote healing in minor injuries of the body or for application around the neck or limbs.	A

14	Ice collar	Intended to alleviate pain and/or promote healing in minor injuries of the neck, throat, and/or head and to alleviate a sore throat.	A
15	Implantable intrathecal infusion pump	A device designed to be implanted in a patient for the storing and subarachnoid (intrathecal) administration of narcotics/drugs to manage intractable pain and muscle spasms of malignant or non-malignant origin.	D
16	Implantable lumbar neuromuscular electrical stimulation system	The system is designed to deliver episodic electrical stimulation to nerves that innervate lumbar muscles to elicit contraction for the treatment of chronic low back pain (CLBP).	D
17	Inflatable hot/cold therapy pack/electric pump	A assembly of devices intended for localized thermal and compression therapy to facilitate the treatment of a variety of adverse conditions resulting from musculoskeletal injury.	B
18	Inhalational analgesia unit	A device primarily designed to administer analgesic gases to the patient, or produce analgesic vapours for inhalation.	B
19	Intervertebral disc prolapse therapy pack	A device intended to be applied to the skin overlying an affected area of the spine (cervical or lumbar) to reduce pain associated with a prolapsed (herniated) intervertebral disc.	B
20	Intubation teeth protector	A device designed to fit over the upper and lower sets of teeth to protect them from damage during endotracheal (ET) tube intubation procedures.	A
21	Inversion table	A fixed framework with a tilting table platform designed to support the body of a patient and provide traction for the back muscles and spine by allowing the patient manually invert their entire body in a supine position (feet up and head down), thereby assist patients eliminate/alleviate back pain.	A
22	Massage table/couch	A table designed for various kinds of complementary therapy.	A
23	Neurophysiologic monitoring system	An assembly of devices designed to monitor and provide electrical stimuli to spinal nerves or other neural pathways during intraoperative surgery or intensive care, typically to reduce the incidence of accidental injury during instrumented spine surgery, or to diagnose acute dysfunction in corticospinal conduction.	C
24	Pain-relief phototherapy skin patch	A skin patch designed to reflect the naturally emitted infrared energy back into the body, with a reduced range of wavelength, intended to provide comfort and localized temporary relief of body aches and pains by phototherapeutic stimulation of strategic points on the skin.	B
25	Sitz bath	A tub filled with water, that is heated by its heating elements and circulated by its agitators, intended for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.	A
26	Sitz bath chair	A device designed to be sat upon by a patient in a powered sitz bath for external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.	A

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (199) **Date: 13 SEP 2021**

Subject: Classification of medical device pertaining to Operation Theatre under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix-A

File No. 29/Misc./03/2020-DC (199)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
Notice

Classification of Medical Devices Pertaining to Operation Theatre

S. No.	Device name	Intended Use	Risk Class
1	Distractor/Retractors	A surgical device used to separate connected surfaces, and to retain their positions to allow a surgical operation to be performed.	A
2	Suction system portable, Electrical/Pneumatic	A device that generates negative pressure used for such treatment as the aspiration of liquid or granular substances.	A
3	Suction system operated by vacuum	A device used for such treatment as the aspiration of liquid or granular substances by using negative pressure supplied by the hospital's medical gas supply system at bed side for using on patient.	A
4	Operation table system	A complete surgical table system intended change the patient's position and enable attaching various table accessories that aid in surgery.	A
5	General-purpose diagnosis/treatment table	A table for general diagnosis and procedures in examination room to aid in patient examination.	A
6	Surgical light system	An illuminator device intended to providing optimial light and colour renderingn to aid in performing surgery.	A
7a	Non-sterile Hemostatic clip applier	A surgical device designed to apply a hemostatic clip for ligation of a blood vessel.	A
7b	Sterile Hemostatic clip applier	A surgical device designed to apply a hemostatic clip for ligation of a blood vessel.	B
8	Hemostatic knife	The blade intended to transmits heat directly to body tissues to achieve hemostasis.	B
9a	Non-sterile Scalpel	An instrument used to sever and separate body tissues during surgery.	A
9b	Sterile Scalpel	An instrument used to sever and separate body tissues during surgery.	B
10	Scalpel blade	A blade intended to be attached to the handle of scalpel.	B
11a	Non-sterile Surgical forceps	A surgical or dental device that is used to clamp and sever the cartilage, bone and other hard tissues.	A
11b	Sterile Surgical forceps	A surgical or dental device that is used to clamp and sever the cartilage, bone and other hard tissues.	B
12	General-purpose electrosurgical unit	A unit used to resect/ablate the tissue or to coagulate the incision/wound site with high-frequency waves.	C
13	Long-term use enterostomy feeding tube	A hollow device to be placed surgically in the stomach, duodenum or jejunum to provide enteral nutrition. It is for long-term use.	C
14	Warming high-flow infusion pump	A device to be used for heating and rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries.	C
15	High-flow blood transfusion pump	A device to be used for rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries.	C

16a	Non-sterile Staple remover	A metal or plastic surgical instrument used to remove staples from a surgical wound or incision that no longer requires stapling to stay closed.	A
16b	Sterile Staple remover	A metal or plastic surgical instrument used to remove staples from a surgical wound or incision that no longer requires stapling to stay closed.	B
17a	Non-sterile Surgical punch	A surgical instrument used to create a hole for suturing or anastomosis of a tissue, blood vessel, etc.	A
17b	Sterile Surgical punch	A surgical instrument used to create a hole for suturing or anastomosis of a tissue, blood vessel, etc.	B
18a	Non-sterile Surgical file	A manually operated, hand-held surgical instrument with a series of bumps or teeth on its surface that is used to smooth out, grind off, or sever tissues.	A
18b	Sterile Surgical file	A manually operated, hand-held surgical instrument with a series of bumps or teeth on its surface that is used to smooth out, grind off, or sever tissues.	B
19a	Non-sterile Blood vessel surgical stripper	A surgical instrument used for complete or partial vascular resection.	A
19b	Sterile Blood vessel surgical stripper	A surgical instrument used for complete or partial vascular resection.	B
20a	Non-sterile Surgical probe	The device is used to explore sinuses, fistulae, and other cavities and wounds.	A
20b	Sterile Surgical probe	The device is used to explore sinuses, fistulae, and other cavities and wounds.	B
21	Multiparameter monitor with critical parameters	A unit that collects monitoring parameters (include an electrocardiogram (ECG), blood pressure, body temperature, cardiac output, and respiratory gases; in addition, other critical parameters (supporting detection of arrhythmia or apnea; and in the case of anesthesia, determination of dose levels of a relaxant or local anaesthesia) using an embedded function kit, module, or other devices to display data, by bed or by patient.	C
22	Surgical robot unit	An operation support device used in open surgery or endoscopic surgery that performs treatment of tissues including suturing, detaching and severing, and installing a prosthesis.	B
23	Motorized diagnostic imaging view box	A device equipped with an electric mechanical or software controlled motor that retains, retrieves, and projects light for direct observation of medical images taken using a variety of methods such as X-ray, magnetic resonance (MR), CT, and ultrasound, and recorded in radiographic film.	A
24	General-purpose manually-operated operation table	A completely mobile surgical table (general-purpose) that has been improved to make it usable for almost all parts of the body that require surgery. Manual or hydraulic operation.	A
25	Powered general-purpose operation table	A completely mobile surgical table (general-purpose) that has been improved to make it useable for almost all parts of the body that require surgery. Electrically line or battery operated.	A
26	Operation table system	A system that consists of several components that form a complete surgical table system. It is used to replace tabletops, change the patient's position, and transfer the patient to and from the operating room. Usually, it consists of columns, a removable tabletop, remote controller for the trolley, and a trolley.	A

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (143) **Date:** 13 SEP 2021

Subject: Classification of Medical Device pertaining to Nephrology and Renal Care under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc./03/2020-DC (143)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

NOTICE

Classification of Medical devices pertaining to Nephrology and Renal Care

S. No.	Medical Device Name	Intended Use	Risk Class
1	Absorbable peritoneum catheter cuff	Intended to maintain stable contact between the skin and the peritoneal dialysis catheter, and prevents bacterial invasion from the outlet. It is embedded subcutaneously at the outlet of the peritoneal dialysis catheter.	D
2	Automated peritoneal dialysis system	An active medical devices intended to perform peritoneal dialysis.	C
3	Urinary stone retrieval basket	Intended to remove urinary stones (renal calculi) from the body during an endoscopic procedure.	B
4	Chair, Haemodialysis, Electrically powered/Manual.	Intended to support the patient in a seated or reclined posture during haemodialysis procedures.	A
5	Collagen-containing peritoneum absorbable catheter cuff	A cuff that consists of biodegradable porous material containing collagen, intended to be embedded subcutaneously at the outlet of the peritoneal dialysis catheter.	D
6	Crimp for plier, Haemodialysis	Intended to manipulate the arteriovenous shunt of patients required hemodialysis.	A
7	Dialyser connector	Intended to connect between a dialysis fluid circuit and dialyzer, etc.	B
8	Dialysis apheresis unit, Therapeutic	Intended to filtrates the blood and separates the plasma, and extracts specific substances in the plasma (e.g., LDL-cholesterol). Then, the plasma is passed through the filtration column in the device and the specific substances that are combined with various substrates are extracted.	C
9	Disposable Hemoperfusion Cartridge	Intended in hemoperfusion machine to thoroughly remove the endogenous and exogenous materials such as residual drugs, toxins and metabolic substances in patients by means of adsorption of synthetic resin and extracorporeal blood circulation.	C
10	Electrical conductivity measuring instrument for dialysis fluid	Intended to determine the concentration of dialysis fluid supplied to a dialyzer based on the measurement of electrical conductivity of dialysis fluid (usually it is electrically measured)	C
11	Flexible fibreoptic nephroscope	Intended for the visual examination of internal structures and treatment of the kidney (eg: renal calcus) by inserting percutaneously into the renal pelvis during nephroscopy.	B

12	Haemodialyzer reprocessing system	Intended to clean (incl. rinsing, cleaning, testing and record keeping of process) and disinfect haemodialysis dialyzers after each use so that they can be reused.	C
13	Haemofilters	A filter used in the process of haemofiltration, to allow for the removal of toxins and/or the replacement of electrolytes.	C
14	Hemodiafiltration system	A device used for blood purification with a hemodiafilter.	C
15	Hemodialysis blood tubing/Extracorporeal systems for blood purification	Sterilized blood tubing intended for hemodialysis (including hemofiltration and hemodiafiltration).	B
16	Hollow-fibre haemodialysis dialyser	Hollow fiber filter intended to remove impurities/fluid from the blood of a patient via haemodialysis machine.	C
17	Kidney donor-organ preservation/transport system	A dedicated system designed to support and maintain a donated kidney organ during transport from the donor to the receiver hospital where the organ will be transplanted into the recipient.	C
18	Kidney stone filter	A filter intended to be placed in the urinary duct to prevent a renal stone from moving from the kidney into the bladder.	C
19	Laser lithotripsy fibre/suction guide	Intended to function as a channel for insertion of the laser fibre of a laser beam guide (e.g., of a general/multiple surgical laser system) in nephroscope, and for removal of debris (e.g., fluid, calculi fragments) when connected to a vacuum source.	B
20	Multi-patient dialysis fluid delivery system	Intended to prepares dialysis fluid for hemodialysis using an artificial kidney, capable of supplying dialysis fluid for two or more patients.	C
21	Peritoneal dialysis catheter adaptor	Intended to connect (devices of different makers and makes devices compatible with each other) a catheter for peritoneal lavage to an external device that manages dialysates.	B
22	Peritoneal dialysis catheter guidewire	A guidewire used temporarily for correction of the position of a peritoneal dialysis catheter.	B
23	Peritoneal dialysis dialysate warmer	Intended to heat the dialysate to within on degree, of kidney patient who is on continuous ambulatory peritoneal dialysis (CAPD), body temperature prior to infusion.	C
24	Peritoneal dialysis ultraviolet irradiation unit	intended for ultraviolet irradiation for disinfection of components of peritoneal dialysis transfer tube set.	B
25	Reverse Osmosis Unit (for dialysis)	Intended to be used with haemodialysis to produce water through reverse osmosis with quality suitable for use with haemodialysis equipment.	C

26	Rigid nephroscope	Intended for visual examination, diagnosis, and treatment of the kidney, renal pelvis, major calyces, and minor calyces by percutaneously inserting scope into the renal pelvis.	B
27	Shunt thrombus suction set	A set used to suction a thrombus developing inside an arteriovenous shunt (external shunt) during procedures including hemodialysis.	B
28	Portable continuous peritoneal perfusate thermal conditioner	A device that heats the peritoneal perfusate before injection into the peritoneal cavity. The perfusate is usually heated through direct contact of the dialysis fluid bag with the radiant heat source.	B
29	Citric acid haemodialysis system cleaning cartridge	Intended for the in-line preparation of a citric acid solution to clean/disinfect the fluid pathways of the system (remove calcium and magnesium deposits) in combination with a heat disinfection program.	B
30	Extracorporeal circuit waste bag	Intended to be used for the collection of waste fluids during preparation and processing of an extracorporeal circuit (e.g., haemodialysis, haemofiltration, apheresis, adsorption treatment), including the collection and rinsing of ultrafiltrate fluid which may contain blood components.	B
31	Haemodialysis Concentrate	Intended to remove metabolic waste from the blood to help maintain physiological blood electrolyte and pH levels while haemodialysis is performed	C
32	Haemodialysis conductivity standard solution	Intended to calibrate conductivity meters used to test the conductivity of dialysate, dialysate concentrate, and water treatment systems used with haemodialysis delivery systems.	C
33	Haemodialysis dialysate water chlorine test kit/strip	Intended to be used to rapidly indicate, through colour change, the concentration of total chlorine in water used to prepare dialysate solution for haemodialysis.	B
34	Haemodialysis system air/foam detector	Intended to identify air bubbles and/or foam in blood returned to the body [usually through an arteriovenous fistula (AVF)] by the extracorporeal blood circuit of a haemodialysis system.	C
35	Hemodialysis system bicarbonate mixer	Intended to mixes two concentrates, A and B, plus water, to the dialysis solution (dialysate) and monitors the mixture.	C
36	Haemodialysis system central monitor	Device intended to connect with multiple haemodialysis systems in order to aid monitoring several dialysis treatments simultaneously.	C
37	Haemodialysis system plasma filtration unit	An electrically-powered integral unit of a haemodialysis system that allows for the removal of plasma from the blood and the infusion of an equal amount of plasma replacement solution to the blood.	C
38	Peritoneal dialysis system dialysate filter	A microporous device used to capture contamination particles of the dialysate before its instillation into the peritoneal cavity.	C

39	Sodium carbonate haemodialysis system cleaning cartridge	Intended to be connected to the fluid circuit of an institutional haemodialysis system for the in-line preparation of a sodium carbonate solution to clean the fluid pathways of the system (remove organic deposits, fats, proteins) in combination with a heat disinfection program.	C
40	Peritoneal Dialysis Transfer Set	A transfer set is tubing that you use to connect your catheter to the bag of dialysis solution. It consists of tubing, connectors etc.	B
41	Peritoneal Dialysis Catheter	That allows dialysis fluid to enter the abdominal cavity, dwell inside for a while, and then drain back out again	B
42	Hemodialysis Catheter (Long Term)	A dialysis catheter is a catheter used for exchanging blood to and from the hemodialysis machine from the patient. The dialysis catheter contains two lumens: Venous. Arterial	C
43	Hemodialysis Catheter	A catheter used for exchanging blood to and from the haemodialysis machine from the patient.	B
44	Single Needle Hemodialysis Catheter/ Blood lines	The single-needle dialysis, in which case only one cannula or a single lumen catheter is used to access the blood.	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (198) **Date: 13 SEP 2021**

Subject: Classification of medical device pertaining to Software under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix-A

File No. 29/Misc./03/2020-DC (198)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
Notice

Classification of Medical Devices Pertaining to Software

S.No	Device Name	Intended Use	Risk Class
1	Continuous Glucose Monitor Retrospective Data Analysis Software	Continuous glucose monitor retrospective data analysis software is intended to analyze and correlate retrospective data from a continuous glucose monitoring device.	A
2	Continuous Glucose Monitor Secondary Display	The purpose of the continuous glucose monitor secondary display is to notify another person, the follower, of the patient's continuous glucose monitoring system sensor glucose information in real time.	B
3	Insulin Pump Secondary Display	The purpose of the insulin pump secondary display is to notify another person of the patient's insulin pump usage information in real time.	B
4	Insulin Pump Therapy Adjustment Calculator For Healthcare Professionals	An insulin pump therapy adjustment calculator for healthcare professionals is intended to recommend insulin pump therapy parameter adjustments (e.g., basal rate, insulin to carbohydrate ratios, insulin sensitivity factors) based on data from external devices, including continuous glucose monitors. The device is software with a graphical user interface.	C
5	Coronary Vascular Physiologic Simulation Software	A coronary vascular physiologic simulation software device is intended to aid in the identification of functionally significant cardiovascular disease by performing offline analysis of pre-existing imaging data to simulate blood flow in the coronary vasculature.	C
6	Multivariate Vital Signs Index	Automated calculation of a summary index (or indices) based on several individual measured vital sign inputs. Collects measured parameter inputs and automates the calculation of a summary index based on those parameters	B
7	Electrocardiograph Software for home use.	Device intended for home use which creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias.	B
8	Photoplethysmograph Analysis Software for home use.	Photoplethysmograph analysis software device for home analyzes of photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a clinical diagnosis.	B
9	Angiographic Coronary Vascular Physiologic Simulation Software	An angiographic coronary vascular physiologic simulation software device is intended to aid in the identification of functionally significant cardiovascular disease.	C

10	Software For Visualization Of Vascular Anatomy And Intravascular Devices	Visualization and measurement of blood vessels and intravascular devices for preoperational planning.	C
11	Orthodontic Software	The device is software that is to be used for the diagnosis and treatment planning of orthodontic patients and conditions.	C
12	Dental Abutment Design Software For Dental Laboratory	The software device is intended to aid in the restoration of chewing function by allowing a dental laboratory or dental clinician to design the patient-specific component of a dental abutment (i.e. abutment collar and abutment post) and CAM or create that component at a dental office or dental laboratory following the directions of the dental implant system.	C
13	Diagnostic Software, K-Nearest Neighbor Algorithm, Autoimmune Disease	The device is intended to suggest a systemic autoimmune disease association as an aid for differential diagnosis to be evaluated in conjunction with clinical findings and other laboratory tests.	B
14	Neuropsychiatric Interpretative Electroencephalograph Assessment Aid	Intended as an aid to provide an interpretation of the patient's neuropsychiatric condition.	C
15	Normalizing Quantitative Electroencephalograph Software	Post-hoc statistical analysis of electroencephalograph signals with comparison to a normative database for interpretation by a qualified clinical user.	C
16	Index-Generating Electroencephalograph Software	Analyze electrical activity of the brain by transformation of electroencephalograph signals into a dimensionless index number for use and interpretation by a qualified clinical user.	C
17	Source Localization Software For Electroencephalograph Or Magnetoencephalograph	Correlation of electrical activity of the brain using various neuroimaging modalities for source-localization	C
18	Automatic Event Detection Software For Polysomnograph With Electroencephalograph	Automatically mark electroencephalograph and polysomongraph signals in order to aid in identification of such events and annotation of prolonged PSG traces; Automatically calculate simple measures obtained from recorded signals (e.G. Magnitude, time, frequency and simple statistical measures of marked events); All output subject to verification by qualified clinical user	C

19	Automatic Event Detection Software For Full-Montage Electroencephalograph	Automatically mark or identify electroencephalograph waveforms for spikes, electrographic seizures, seizure-like events in order to aid in identification of such events and help review and annotation of prolonged EEG traces; All output subject to verification by qualified clinical user	C
20	Computerized Cognitive Assessment Aid For Concussion	For use as an assessment aid in the management of concussion.	C
21	Ataxiagraph With Interpretive Software	Device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed and provides interpretation or clinical implication of the measurement.	A
22	Computerized Behavioral Therapy Device For Psychiatric Disorders	The device is intended to provide cognitive behavioral therapy to treat substance use disorder. The device is a software-based mobile app downloaded onto a smartphone.	C
23	Brain Injury Adjunctive Interpretive Oculomotor Assessment Aid	A traumatic brain injury eye movement assessment aid is a prescription device that uses a patients tracked eye movements to provide an interpretation of the functional condition of the patients brain.	C
24	Device, Fertility Diagnostic, Contraceptive, Software Application	Designed to monitor and provide fertility information to prevent pregnancy (contraception).	C
25	Diabetic Retinopathy Detection Device	A retinal diagnostic software device is a software device that incorporates an adaptive algorithm to evaluate ophthalmic images for diagnostic screening to identify retinal diseases or conditions.	C
26	Colon Computed Tomography System, Computer Aided Detection	To assist radiologists in the review of multi-slice computed tomography (msct) exams of the colon and highlight potential polyps that the radiologist should review.	B
27	Lung Computed Tomography System, Computer-Aided Detection	To assist radiologists in the review of multi-slice computed tomography (msct) exams of the chest and highlight potential nodules that the radiologist should review.	B
28	Chest X-Ray Computer Aided Detection	To assist radiologists in the review of chest radiographic images and highlight potential nodules that the radiologist should review.	B

29	Computer-Assisted Diagnostic Software For Lesions Suspicious For Cancer	Assist clinical users in characterizing lesions identified on acquired medical images	C
30	Radiological Computer Assisted Detection/Diagnosis Software For Fracture	A radiological computer assisted detection and diagnostic software for suspected fracture is an image processing device intended to aid in the detection, localization, and/or characterization of fracture on acquired medical images (e.g. radiography, MR, CT).	B
31	X-Ray Angiographic Imaging Based Coronary Vascular Simulation Software Device	X-ray angiographic imaging based coronary vascular simulation software device is a device that provides an image analysis tool to assess blood flow in the coronary vascular system using X-ray angiographic imaging data. And yields simulation-based metrics for certain cardiology applications which aid clinical user.	B
32	Automated Radiological Image Processing Software	To provide automated radiological image processing and artificial intelligence based analysis tools.	B
33	Image Acquisition And/Or Optimization Guided By Artificial Intelligence	A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals.	B
34	Burn Resuscitation Decision Support Software	The burn resuscitation decision support system (BRDSS) is intended for use in prediction of hourly fluid volume during initial 24 hours of burn resuscitation. It is intended for patients who have greater than 20% total body surface area burn.	C
35	Software, Similarity Score Algorithm, Tissue Of Origin For Malignant Tumor Types	This test is intended to measure the degree of similarity between the RNA expression pattern in a patient?s fresh-frozen tumor and the RNA expression patterns in a database of tumor samples for some common malignant tumor types that were diagnosed according to then current clinical and pathological practice.	C
36	Software for peritoneal dialysis treatment	A software that performs prescription simulation of peritoneal dialysis based on the results obtained from a peritoneal function test (PFT), a peritoneal equilibration test (PET) and a body composition analyzer. It supports preparation of a dialysis treatment plan.	C
37	Software for radiation planning	A software that calculates and displays the area to be treated with radiation and the internal dose distribution based on the results obtained with CT systems etc. , and supports the radiotherapy planning.	C

38	Software for radiotherapy QAQC planning	A software that verifies the validity of the radiotherapy plan by recalculation of the dose and the MU value calculated with the radiotherapy planning system software and radiotherapy planning system.	C
39	Software for ophthalmic surgery treatment planning	A software for intended to aid ophthalmic surgical planning based on measurement of the eye prior to the surgery. It simulates surgical results.	C
40	Software for active implanted device control	A software used to transmit one or more electrical operating characteristics noninvasively to the active base unit and change the characteristics.	C
41	Information collating software for radiotherapy	A software that has function of collating the information such as irradiation parameter specified by a radiation planning software, and the condition that a radiotherapy equipment irradiates, on the occasion of the irradiation of X-ray in the radiotherapy.	C
42	Software for gene variants analysis (for cancer genome profiling)	A software for gene variants analysis which is designed to perform cancer genome profiling based on information of gene variants obtained from body tissue samples.	C
43	Supporting software for differential diagnosis with endoscopic imaging	A software, which is designed to process data obtained from an endoscopic image. The resultant data are provided for diagnostic, etc. It has functions to output numeric values and graphs based on quantitative data such as benign/malignant differentiation of lesion candidates, presenting candidates of diagnostic outcomes, and stage of disease progression.	C
44	Chairside dental CAD/CAM unit	Intended for computer-aided design (CAD) or computer-aided manufacturing (CAM) of dental restorations.	B
45	Software for using with mammography-combined diagnostic X-ray system	A software, which is designed to processes data obtained from a combined diagnostic mammography-radiography system.	B
46	Software for public thoracic and abdominal health screening diagnostic X-ray system	A software, which is designed to process data obtained from a thoracic and abdominal public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	B
47	Software for visual evoked response stimulator	A software, which is designed to process data obtained from a visual evoked response stimulator. The resultant data are provided for diagnosis, etc.	B

48	Software for auditory evoked response stimulator	A software for medical device, which is designed to process data obtained from an auditory evoked response stimulator. The resultant data are provided for diagnosis, etc.	B
49	Software for pulmonary exercise stress monitoring system	A software, which is designed to process data obtained from a pulmonary exercise stress monitoring system.	B
50	Software for ECG recorder with real-time analysis	A software, which is designed to process data obtained from an ECG recorder with real-time analysis. The resultant data are provided for diagnosis, etc.	B
51	Software for film-recorded digital radiography	A software, which is designed to process data obtained from a film-recorded digital radiography. The resultant data are provided for diagnosis, etc.	B
52	Software for dye dilution cardiac output calculator	A software, which is designed to process data obtained from a dye dilution cardiac output unit. The resultant data are provided for diagnosis, etc.	B
53	Software for urodynamic measurement system	A software, which is designed to process data obtained from a urodynamic measurement system. The resultant data are provided for diagnosis, etc.	B
54	Software for vestibular function caloric stimulator	A software, which is designed to process data obtained from a vestibular function caloric stimulator. The resultant data are provided for diagnosis, etc.	B
55	Surporting software for external fixators treatment plan	A software that analyzes information useful for bone fracture and for correction of bone deformities based on information collected from diagnostic X-ray systems, etc. or based on information entered in a therapeutic apparatus, and supports preparation of a treatment plan with external fixators.	B
56	Diagnostic supporting software for diabetes	A software that supports analysis and assessment of therapeutic effects of diabetes treatment by processeing information collected from a blood glucose meter, etc into the data related to changes or trends in blood glucose levels.	B
57	Quantitative calculation software for IGC test	A software that performs quantitative calculation of blood flow in relation to a brightness time change based on information obtained from video images of indocyanine green angiography.	B
58	Analyzing software for hemodynamics or cardiac function	A medical device program that analyzes hemodynamics or cardiac function based on information obtained from diagnostic imaging systems, etc. and uses the results for diagnosis.	B

59	Supporting software for root canal treatment	A software for medical device, which is used to support preparation of a treatment plan based on information collected from diagnostic imaging systems, etc. in the root canal treatment.	B
60	Ventilator, software	A data program designed for use in, or together with, a ventilator allowing it to function according to the intended purpose. The software can be installed, or exchanged as an upgrade.	C

Note 1 - As per clause (iii) of Part I of First Schedule of Medical Devices Rules 2017, Software, which drives or influences the use of a device, falls automatically in the same class.
Note 2 - Any add-on to the same software will be treated as same risk class.

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (201) **Date:** 27 SEP 2021

Subject: Classification of Medical Device pertaining to Neurological under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File.No.29/Misc/03/2020-DC (201)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA, Bhawan, new Delhi-110002

Notice

Classification of Medical Devices Pertaining to Neurological

Sr. No.	Device Name	Intended Use	Risk Class
1	Analgesic PENS system	Intended to deliver controlled electrical impulses directly to the subcutaneous tissue (i.e., invasively) in the vicinity of a peripheral nerve as relief of chronic neuropathic pain.	B
2	Analgesic TENS system	Intended to treat pain by transcutaneous electrical simulation on peripheral nerves.	B
3	Analytical non-scalp cutaneous electrode	Electrical conductor designed to be attached to the skin surface of a patient outside of the hair line (i.e., non-scalp) to conduct electrical signals to a parent device for electrophysiological recording/monitoring.	A
4	Analytical non-scalp cutaneous lead	Intended to conduct electrical signals between a skin electrode(s) or needle electrode(s) [electrode not included] and a device designed for electrophysiological recording/monitoring [e.g., electromyography (EMG), evoked potentials (EP), bioelectrical impedance].	A
5	Analytical scalp electrode	Intended to be attached to the scalp surface of a patient to transmit changes in the electrical potential of various areas of the brain for recording/monitoring by a connected parent device [i.e., an electroencephalograph (EEG), sleep, or evoked potential recording device].	B
6	Analytical scalp lead	Intended to connect an electroencephalographic electrode(s) to an electroencephalographic system to facilitate the transmission of the electrical signals during encephalography (EEG).	B
7	Aneurysm clip.	An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting	D
8	Antiseizure/psychiatric-therapy vagus nerve electrical stimulation system	Implantable device intended to apply periodic electrical stimuli to the vagus nerve to help control seizures and/or to help treat psychiatric disorder symptoms (e.g., depression).	D
9	Atrial cerebrospinal fluid catheter	Intended to be implanted as the distal component of a ventriculoatrial shunt to channel cerebrospinal fluid (CSF) to the right atrium where it can be absorbed into the body.	D
10	Autonomic neuropathy heart rate meter	Intended to diagnose autonomic nervous system dysfunction (autonomic neuropathy).	C

11	Bare-metal intracranial vascular stent	Intended to be implanted into the base or parent artery of an intracranial aneurysm.	D
12	Behavioural therapy electrical stimulation system	Intended in the treatment of obsessive/compulsive behaviour and drug abuse, by applying electrical impulse(aversion therapy).	C
13	Bladder/bowel-evacuation implantable electrical stimulation system	Intended to empty the urinary bladder and/or the bowels by applying electrical stimuli typically to the cone-shaped end of the spinal cord (conus medularis).	D
14	Brain injury adjunctive interpretive electroencephalograph assessment aid.	A brain injury adjunctive interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A brain injury adjunctive interpretive EEG assessment aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis	C
15	Brain-responsive electrical stimulation system	Intended to continuously monitor brain activity and deliver electrical stimuli to seizure foci in response to neurological disorders (e.g., epilepsy).	D
16	Cardiac-therapy vagus nerve electrical stimulation system	Intended to apply periodic stimuli to the vagus nerve as a treatment for cardiac failure.	D
17	Cerebral perfusion catheter	Intended for brain protection during profound hypothermic circulatory arrest during aortic surgery.	D
18	Cerebrospinal fluid manometer,	Intended to measure the cerebrospinal fluid (CSF) pressure/intracranial pressure via lumbar puncture.	C
19	Cerebrospinal fluid shunt valve programmer	Intended to noninvasively modify the operating pressure of a programmable, non-active, implanted cerebrospinal fluid (CSF) shunt valve that is part of a CSF shunt.	C
20	Coma-arousal vagus nerve electrical stimulation system	Intended to apply periodic stimuli to the vagus nerve for the purpose of exciting the patient to arousal from a vegetative state (i.e., a deep coma).	D
21	Cortical electrode.	A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity	D

22	Cranial bur,	Intended to fit into an appropriate powered handpiece that provides the rotation allowing the user to excavate soft or hard skull tissue.	A
23	Cranial electrotherapy stimulator.	A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety	D
24	Cranial perforator	Metallic rotary endpiece designed to cut a hole(s) or a circular section(s) of the skull vault (calvarium) by attaching to powered drill/handpiece.	B
25	Cranial trephine,	Intende as a neurosurgical blade used to cut/remove circular sections of the skull vault (calvarium) to provide access to the interior	A
26	Craniotomy power tool system handpiece	Intended to be used to rotate a cranial cutting tool (i.e., a drill bit, bur, trephine or perforator) in order to produce a hole or holes in the skull vault (calvarium).	C
27	Cryogenic surgical device.	A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site	D
28	Cutaneous electrode.	A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation	B
29	Deep brain electrical stimulation system	Designed to apply electrical stimuli to specific areas of the deep brain for the treatment of movement disorders, psychiatric disorders and/or to treat chronic, severe, intractable pain.	D
30	Deep brain electrical stimulation system lead	Intended to be implanted in specific areas of the deep brain and used along with deep brain electrical simulation system.	C
31	Depth electrode.	A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain	C
32	Diagnostic peripheral nerve electrical stimulation system	Intended to apply electrical stimuli in one peripheral region of the body while the response is monitored in another peripheral region.	C
33	Diagnostic somatosensory tactile stimulation system	Intended to be used to apply tactile stimuli to the body (e.g., pneumatic activation of a membrane to the fingers and lips) typically for evoked response procedures to investigate the function and potential disorders of the brain.	B
34	Diskectomy system, percutaneous, automatic	Intended for the percutaneous (through the skin) removal of the nucleus pulposus from the lumbar disc.	D
35	Dura mater sealant	Intended to be applied to sutured dura mater to prevent cerebrospinal fluid (CSF) leakage during healing.	C

36	Echoencephalograph.	An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head	C
37	Ejaculation electrical stimulation system	Intended to apply electrical stimuli to the nerves that control ejaculation.	C
38	Electroconvulsive therapy system	Intended to apply strong electrical stimuli to a patient's brain to induce convulsions and loss of consciousness, typically to treat major depression, schizophrenia, or mania.	C
39	Electroencephalogram (EEG) signal spectrum analyzer.	An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal	B
40	Electroencephalograph electrode/lead tester.	An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin	B
41	Electroencephalograph test signal generator.	An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph	B
42	Electroencephalograph tester	Intended to perform quality control procedures on an electroencephalograph (EEG) machine and/or a sleep recording machine.	A
43	Electroencephalograph.	An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head	C
44	Electroencephalographic electrode cap	Analytical scalp electrodes preconfigured within a head-worn device to use with electroencephalography (EEG).	B
45	Electroencephalographic long-term ambulatory recorder	Intended to continuously record electroencephalographic signals in ambulatory patients for periods usually from 24 to 72 hours to assess a variety of neurological conditions (e.g., epilepsy) and psychiatric disorders.	B
46	Electroencephalographic monitoring system	Intended to continuously measure the electrical signals produced by a patient's brain and display/record them as an electroencephalogram (EEG) to evaluate brain function. Alongwith which measuring of other physiological parameters such as electromyogram (EMG), respiration wave forms, blood pressure, ocular motility, and/or haemoglobin oxygen saturation (SpO2) and carbon dioxide (CO2) in relation to EEG.	C
47	Electromyograph	Intended in clinical diagnosis of muscular disorders to evaluate muscle weakness and to determine if the weakness is related to the muscles themselves or a problem with the nerves that supply the muscles.	B
48	Electronystagmograph	Intended for detecting the electrical potential caused by eye movements.	B

49	Epichantal brain electrical stimulation system	Intended to apply weak, pulsed (not continuous) electrical stimuli from beneath the scalp to specific areas of the brain for the treatment of focal epilepsy.	C
50	Esthesiometer.	An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity	A
51	Extramuscular diaphragm/phrenic nerve electrical stimulation system	Intended to provide ventilatory support to a patient with diaphragm dysfunction of neuromuscular origin through electrical stimulation of the phrenic nerve, to contract the diaphragm rhythmically (using extramuscular electrodes) and cause the patient to draw breath in a manner similar to natural breathing.	D
52	Facial nerve locating system	Intended to locate a facial nerve by applying an electrical stimulus.	B
53	Gait-enhancement electrical stimulation system, external	Intended to improve the gait in a patient suffering from partial paralysis of the lower extremities or other neuromuscular disorders by applying external electrical simulation.	B
54	Gait-enhancement electrical stimulation system, implantable	Intended to improve the gait in a patient suffering from partial paralysis of the lower extremities or other neuromuscular disorders by applying internal electrical simulation.	D
55	Home seizure monitoring system	Intended to detect and record a seizure by continuous measurement of one or more physical/physiological parameters (e.g., body motion, electrical activity of the heart or skeletal muscles) in a patient with epilepsy during daily activities and/or sleep in the home; some types may also be used in clinical settings.	C
56	Human dura mater.	Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater	D
57	Implantable pulse generator mesh bag, bioabsorbable	Intended to envelop an implantable pulse generator (IPG) (e.g., cardiac pacemaker/defibrillator, neurostimulator) to stabilize the implant in the subcutaneous pocket in which it is implanted.	D
58	Implantable spinal cord electrical stimulation system programmer	Device designed to change, telemetrically, one or more of the operating parameters (the programs) of an implanted spinal cord electrical stimulation system pulse generator (EPG).	C
59	Implanted cerebellar stimulator.	An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.	D

60	Implanted diaphragmatic/phrenic nerve stimulator.	An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D
61	Implanted intracerebral/subcortical stimulator for pain relief.	An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D
62	Implanted neuromuscular stimulator.	An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe	D
63	Implanted spinal cord stimulator for bladder evacuation.	An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver	D
64	Intracranial pressure monitor device	Intended for intermittent or continuous measurement and display of intracranial pressure (ICP). It is used in conjunction with an invasive intracranial device.	D
65	Intramuscular diaphragm/phrenic nerve electrical stimulation system	Intended to provide ventilatory support to a patient with diaphragm dysfunction of neuromuscular origin through electrical stimulation of the phrenic nerve to contract the diaphragm rhythmically (using intramuscular electrodes) and cause the patient to draw breath in a manner similar to natural breathing.	D

66	Intramuscular diaphragm/phrenic nerve electrical stimulation system programmer	Intended to change, telemetrically, one or more of the operating parameters (the programs) of an intramuscular diaphragm/phrenic nerve electrical stimulation system external pulse generator (EPG).	C
67	Intranasal cooling system	Intended for rapid cooling induction in patients where temperature reduction is clinically indicated (e.g., following a cerebral ischemic event, during cardiac arrest) to help mimimize damage to the brain and heart.	C
68	Invasive-detection physiological monitor	Intended for continuous or intermittent measurement, display and/or recording of several invasively-detected physiological parameters [e.g., intracranial pressure (ICP), compartmental pressure].	C
69	Leukotome	Intended to cut brain tissue (i.e., cutting white matter, leukotomy).	B
70	Magnetoencephalography system	Intended to non-invasively detect, measure, and display bio-magnetic signals produced by electrically-active cortical brain tissue, and that provide diagnostic information about the location of the active tissue responsible for cognitive brain functions relative to the surrounding brain anatomy	B
71	Manual surgical saw, flexible	Intended for cutting bone through a sawing action during neurological or orthopaedic surgery.	B
72	Meningeal prosthesis	Intended to repair the meningeal membrane (meninges).	D
73	Nasopharyngeal electrode.	A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity	C
74	Needle electrode.	A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals	C
75	Nerve conduction velocity measurement device.	A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time	C
76	Nerve guide, bioabsorbable, animal-derived	Collagen matrix material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps.	D
77	Nerve guide, bioabsorbable, synthetic	Synthetic material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps.	D
78	Nerve guide, non-bioabsorbable	Non-bioabsorbable material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps.	D
79	Neurological endoscope.	A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain	C

80	Neurological stereotactic surgery system	Intended to store diagnostic images used for image-guided neurosurgery.	C
81	Neuromuscular transmission electrical skin sensor	Intended to detect electrical neuromuscular transmission (NMT) signals, for assessing the degree of neuromuscular block in a patient.	C
82	Neuromuscular transmission motion sensor	Intended to be placed on the thumb and index finger of a patient to detect movements and convert them into electrical neuromuscular transmission (NMT) signals during nerve stimulation.	B
83	Neuropsychiatric interpretive electroencephalograph assessment aid.	The neuropsychiatric interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis	C
84	Neurosurgical chair	Intended to support and position a patient in a sitting or reclined position during neurosurgery.	A
85	Neurosurgical head holder (skull clamp).	A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures	B
86	Neurosurgical headrests.	A neurosurgical headrest is a device used to support the patient's head during a surgical procedure	A
87	Neurosurgical microscope	Designed to magnify minute structures within the neurological fields for surgery, typically the brain or spine or surroundings in the performance of neurological surgical procedures which require high magnification by transmitted light.	B
88	Neurosurgical ultrasound navigation system	Intended for intraoperative imaging of the brain for precise navigation during brain surgery (e.g., resection of malignant brain tumours, treatment of vascular malformations).	B
89	Non-electroencephalogram (EEG) physiological signal based seizure monitoring system.	A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure	C
90	Nonpowered neurosurgical instrument.	A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc	A
91	Olfactometry system	Intended to determine the response of humans to odours delivered through the nose, including irritants.	C

92	Percussion hammer, manual	Intended to be used by an examining physician to gently tap near a patient's joints to test reflexes.	A
93	Percussor.	A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations	A
94	Photodiode subretinal prosthesis system	Designed to provide visual function to a patient with vision loss due to retinal degeneration by detecting light, converting it into electrical signals, and relaying them to the retina for neural stimulation.	C
95	Physical therapy ultrasound/neuro muscular stimulation system	Designed to produce a rhythmic contraction/release of injured muscles to promote the removal of metabolic by-products while applying ultrasound treatments.	B
96	Pinwheel.	A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation	A
97	Rheoencephalography.	A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area	D
98	Scalp clip.	A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp	C
99	Scoliosis-treatment electrical stimulation system	Intended to apply electrical stimuli to the spinal musculature to produce a force that stabilizes or limits the progression of the spinal lateral curvature (i.e., scoliosis).	D
100	Skull plate anvil.	A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull	A
101	Skull punch.	A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means	A
102	Skullplate screwdriver.	A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws	A
103	Stereotactic neuronavigation/ planning system	Intended to receive and analyse patient magnetic resonance imaging (MRI) images and position landmarks on these images, then register the images by the mean of a three-dimensional (3-D) optical positioning system (frameless stereotactic neuronavigation) to provide real-time relative positioning for the treatment probes and instruments.	B
104	Stereotactic radiosurgical system	Intended to deliver a therapeutic radiation dose to an anatomical region from external beams produced from multiple radionuclide sources arranged in a fixed focal point collimated array; typically used to treat brain, neck, breast and spinal tumours.	D

105	Tibial nerve percutaneous incontinence-control electrical stimulation system	Intended to treat urinary and/or faecal incontinence with electrical stimuli applied to the sacral nerve via percutaneous tibial nerve stimulation (PTNS).	D
106	Transcranial electrical stimulation system, continuous-current and pulsed-current	Intended for one or more psychiatric\neurological therapy types [e.g., transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS)]. And to induce a state resembling that of chemically-induced anaesthesia for treating one or more psychiatric disorders which may include anxiety, depression, insomnia, and/or addiction.	B
107	Transvenous phrenic nerve electrical stimulation control unit	Intended to configure/deliver stimulation of the phrenic nerve, via a transvenous electrode, to cause contraction of the diaphragm in conjunction with mechanical ventilation to assist earlier ventilation weaning.	D
108	Tuning fork	Intended to test the hearing acuity of a patient, to diagnose hearing disorders, and to test for vibratory sense.	A
109	Ultrasonic scanner calibration test block.	An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph)	A
110	Vagus nerve electrical stimulation system programmer	The strength and duration of the electrical impulses are programmed	C

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (182) **Date:** 27 SEP 2021

Subject: Classification of Medical Device pertaining to Gastroenterology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc./03/2020-DC (182)

Drugs Controller General (India)

Directorate General of Health Services

Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Gastroenterology

Sr No.	Medical Device Name	Intended Use	Risk Class
1	Absorbent enteric stomal dressing	To be placed over a continent enteric stoma (surgically-created artificial opening between the intestines and the body surface through which bodily waste is drained from the intestines) to protect it from harmful external influences, which includes absorbent materials intended to protect the surrounding skin from enteric fluids.	B
2	Anal fistula circular cutter	To be intended for the circumferential resection of tissue to treat simple anal fistula	B
3	Anal fistula seton	A sterile implantable cord intended to be placed through an anal fistula tract and tied outside the fistula, forming a loop around the anus, to allow drainage through the fistula for tissue healing.	C
4	Anoscope, reusable	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the anus and rectum.	B
5	Anoscope, single-use	A sterile endoscope with a rigid inserted portion intended for the visual examination and treatment of the anus and rectum.	B
6	Barium enema catheter	A flexible tube designed to administer barium, a contrast medium, into the lower gastrointestinal tract by way of the rectum, for radiographic visualization of the area.	B
7	Bile duct prosthesis	An implantable artificial substitute for the tube-like structure that carries bile from the gallbladder to the duodenum.	C
8	Biliary manometric catheter	A sterile, non-electrical flexible tube intended to be inserted into the biliary tree to measure pressures within the ducts, especially to evaluate sphincter of Oddi function.	B

9	Catheter-balloon inflator, reprocessed	A sterile device designed to manually inflate and regulate the pressure of a balloon catheter (e.g., by injecting and aspirating fluid or air within the balloon), and to deflate the balloon during a medical procedure.It is typically used during angiography, angioplasty, gastrointestinal (GI), or sinuplasty procedures.	B
10	Catheter-balloon inflator, reusable	A device designed to manually inflate and regulate the pressure of a balloon catheter (e.g., by injecting and aspirating fluid or air within the balloon), and to deflate the balloon during a medical procedure.	B
11	Catheter-balloon inflator, single-use	A sterile device designed to manually inflate and regulate the pressure of a balloon catheter (e.g., by injecting and aspirating fluid or air within the balloon), and to deflate the balloon during a medical procedure.	B
12	Cholangiopancreatography catheter, reusable	A flexible tube inserted through a flexible endoscope, after its placement in the duodenum via the oral cavity, for the endoscopic cannulation of the gastrointestinal ductal system (i.e., the pancreatic, hepatic, and/or common bile ducts) during endoscopic retrograde cholangiopancreatography (ERCP).	B
13	Cholangiopancreatography catheter, single-use	A flexible tube inserted through a flexible endoscope, after its placement in the duodenum via the oral cavity, intended for the endoscopic cannulation of the gastrointestinal ductal system (i.e., the pancreatic, hepatic, and/or common bile ducts) during endoscopic retrograde cholangiopancreatography (ERCP).	B
14	Closed-ended intestinal ostomy bag, multiple-piece	A non-sterile plastic pouch designed to be attached around a faecal stoma for use as a receptacle for faeces following a colostomy [the stool (faeces) being generally well formed].	A
15	Closed-ended intestinal ostomy bag, one-piece	A non-sterile plastic pouch designed to be attached with an adhesive to the skin around a faecal stoma and used as a receptacle for faeces following a colostomy [the stool (faeces) being generally well formed].	A
16	Colonic endoscopy cuff	A sterile distal attachment to a flexible endoscope intended to improve endoscopic control and bowel visualization during colonic endoscopy.	B
17	Colonic lavage kit, surgical	A collection of sterile devices intended to be used during open colorectal surgery (bowel resection) to irrigate the colon above (proximal to) the site of a lesion/blockage, prior to surgical anastomosis, when preoperative preparation of the colon has not been possible, normally due to obstruction.	B

18	Colonic mucosa barrier dressing	A non-sterile solution/suspension intended to be introduced into the sigmoid/descending colon as an enema for the treatment of inflammatory bowel disease (e.g., ulcerative colitis). It is intended to create an adhesive physical barrier on the colonic mucosa to protect the mucosa from potentially harmful substances in the distal colon lumen	C
19	Colonoscope positioning sleeve	A non-sterile endoscopic sheath with two inflatable balloons designed to be mounted on a colonoscope to position and stabilize the endoscope within the large intestine of a patient.	B
20	Colonoscope stiffener	A dedicated stiff wire that is inserted into a flexible colonoscope to allow the physician to increase the stiffness of the colonoscope when extra rigidity is required during a colonoscopy.	B
21	Colorectal sizer	A hand-held manual surgical instrument designed to assess colon and/or rectal lumen diameter to aid the selection of an appropriate size intraluminal stapler (i. e, the stapler head) for bowel anastomosis following transection.	B
22	Common bile duct dilator	A hand-held manual surgical instrument designed to dilate the common bile duct, i.e., the union of the cystic and hepatic ducts.	B
23	Duodenal bypass liner	A non-sterile stent-like device with a valve designed to be implanted in the duodenum where it is intended to reduce duodenal nutrient absorption from food to facilitate obese patient weight loss.	C
24	Duodenal-jejunal bypass liner	A sterile stent-like implant designed to function as an impermeable barrier in the duodenum and part of the jejunum for partially-digested food from the stomach (chyme) passing on its inside and bile/digestive enzymes passing on its outside, intended to treat type 2 diabetes mellitus and obesity.	C
25	Endoscope tissue removal cap	A sterile plastic tube designed to be placed onto the distal end of an endoscope (e.g., oesophagoscope) to facilitate the removal of coagulated blood/tissue during electrosurgical treatment (e.g., for the treatment of Barrett's oesophagus).	B
26	Endoscopic biopsy valve, non-sterile	A non-sterile device intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of biomaterial during an endoscopic procedure.	A
27	Endoscopic biopsy valve, sterile	A sterile device intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of biomaterial during an endoscopic procedure.	B

28	Endoscopic cutting stapler connector	A rod-like component of an endoscopic cutting stapler intended to enable connection between the stapler handpiece and the endpiece/loading unit.	B
29	Endoscopic electrosurgical biopsy/resection kit, full-thickness	A collection of sterile devices, which includes an implantable haemostatic ligation clip, intended to be used to obtain a full-thickness tissue biopsy and/or therapeutic resection of gastric, duodenal, colonic, and/or rectal tissue during an endoscopic procedure.	C
30	Endoscopic electrosurgical biopsy/resection kit, partial-thickness	A collection of devices designed to be inserted through a compatible endoscope to obtain a mucosal tissue biopsy and/or therapeutic resection of upper gastrointestinal (GI) tract tissue, typically during endoscopic retrograde cholangiopancreatography (ERCP) procedures.	C
31	Endoscopic electrosurgical electrode/submucosal lift needle	A sterile, invasive, endoscopic device intended to deliver both: 1) a submucosal lifting solution; and 2) an electrosurgical current in a monopolar configuration (i.e., with a return electrode) to tissues for cutting/coagulation.	B
32	Endoscopic gastrointestinal stenosis dilator	A sterile invasive device intended to be used to dilate or expand a narrowing lesion (e.g., oesophageal stricture, stenosis) in the lumen of the gastrointestinal [GI] tract, under endoscopic visualization.	B
33	Endoscopic motorized cutting stapler, reusable	A hand-held, battery-powered surgical instrument designed to be used during endoscopic surgical procedures for the expeditious transection and resection of tissues and the creation of anastomoses.	B
34	Endoscopic motorized cutting stapler, single-use	A sterile, hand-held, battery-powered surgical instrument designed to be used during endoscopic surgical procedures for the expeditious transection and resection of tissues and the creation of anastomoses.	B
35	Endoscopic needleless submucosal lift catheter	A sterile, flexible tube intended to non-invasively deliver a submucosal lifting solution into the submucosa of the gastrointestinal tract through a flexible endoscope during an endoscopic procedure (e.g., gastroscopy, colonoscopy) to lift a lesion, typically for subsequent excision.	B
36	Endoscopic overtube, reusable	A tubular device intended to be used in combination with a compatible flexible endoscope to aid in endoscopic insertions and to secure a pathway for multiple endoscopic intubations during diagnostic and therapeutic endoscopic procedures (e.g., upper and/or lower gastrointestinal (GI) tract endoscopy).	B
37	Endoscopic spray catheter	A sterile, flexible tube intended to be used with an endoscope (e.g., colonoscope) to administer fluids (e.g., dyes for mucosal coloration) in spray form.	B

38	Enema tip, reusable	A non-sterile device made with Hevea natural rubber latex (NRL) intended to be connected to an enema tube to facilitate delivery of an enema solution into the rectum.	A
39	Enema tube	A non-sterile, length of tubing that is used as a conduit between the enema bag and the enema tip for the delivery of the enema solution into the rectum.	A
40	Enteral feeding tube clearing kit	A collection of non-sterile compounds and devices intended to be used to prevent and/or remove, through biochemical action, an enteral formula clog in an in situ enteral feeding tube to maintain luminal patency.	B
41	Enteral feeding/decompression tube clearing stem	A non-sterile, sheath-covered device intended to be used to mechanically clear a clog in an in situ nasogastric, nasoenteral, gastrostomy and/or jejunostomy tube, used for feeding and/or decompression, to maintain luminal patency.	A
42	Enteral tube extension, non-sterile	A non-sterile, thin, flexible tube intended for extracorporeal connection to an enteral feeding tube (e.g., nasogastric tube) to increase the length of tubing from the patient to an oral/enteral device (e.g., syringe) during enteral feeding/medication administration or aspiration.	B
43	Enteral tube extension, sterile	A sterile, thin, flexible tube intended for extracorporeal connection to an enteral feeding tube (e.g., nasogastric tube) to increase the length of tubing from the patient to an oral/enteral device (e.g., syringe) during enteral feeding/medication administration or aspiration.	B
44	Externally-propelled flexible video colonoscope	A non-sterile endoscope with a highly flexible sleeve and distal tip intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract].	B
45	Fistula-repair biomatrix implant	A sterile, bioabsorbable, animal-derived substance intended to be injected into a fistula tract (e.g., anal or rectal fistula) to close it by adding volume and promoting the ingrowth and neovascularization of host tissue.	D
46	Flexible fibreoptic choledochoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the choledoc, better known as the common bile duct (CBD).	B
47	Flexible fibreoptic colonoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B
48	Flexible fibreoptic duodenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B

49	Flexible fibreoptic enteroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the small intestine (the duodenum, jejunum, and ileum).	B
50	Flexible fibreoptic gastroduodenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct].	B
51	Flexible fibreoptic gastroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus and the stomach.	B
52	Flexible fibreoptic oesophagoscope	An endoscope with a flexible inserted portion intended the visual examination and treatment of the oesophagus.	B
53	Flexible fibreoptic pancreatoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment in the pancreas.	B
54	Flexible fibreoptic sigmoidoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum).	B
55	Flexible ultrasound colonoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B
56	Flexible ultrasound duodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B
57	Flexible ultrasound gastroduodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct].	B
58	Flexible video choledochoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the choledoc, better known as the common bile duct (CBD).	B
59	Flexible video choledochoscope, single-use	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the biliary tract and related ducts [e.g., common bile duct (CBD), cystic duct, pancreatic duct], and for the removal of gallstones.	B
60	Flexible video colonoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B

61	Flexible video colonoscope, single-use	A sterile endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract].	B
62	Flexible video duodenoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B
63	Flexible video duodenoscope, single-use	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the duodenum (the first part of the small intestine).	B
64	Flexible video enteroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the small intestine (the duodenum, jejunum, and ileum).	B
65	Flexible video gastroduodenoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct].	B
66	Flexible video gastroscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus and the stomach.	B
67	Flexible video oesophagoscope, reusable	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus. It is inserted into the body through the mouth. Anatomical images are obtained via a camera incorporated at the distal end of the oesophagoscope and are shown on a monitor. This device is commonly used to examine abnormalities in the tissue structure and mucous lining of the oesophagus. This is a reusable device.	B
68	Flexible video oesophagoscope, single-use	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the oesophagus.	B
69	Flexible video pancreatoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment in the pancreas.	B
70	Flexible video sigmoidoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum).	B
71	Gastric sleeve	A sterile implantable device intended to be wrapped around the proximal portion of the stomach to reduce stomach volume and facilitate weight loss in overweight/obese patients by attempting to restrict the quantity of food consumed through an increased sense of satiety (fullness).	C

72	Gastric tonometry catheter	A sterile flexible tube intended for orogastric, nasogastric, or rectal insertion to sample carbon dioxide (CO2) from the mucosal vasculature of the stomach or sigmoid colon for the measurement of partial pressure (i.e., tonometry) of CO2 (pCO2) during diagnosis of mensenteric ischemia.	B
73	Gastrointestinal anastomosis coupler, bioabsorbable	An implantable device intended to be used to join and transect excess tissue of gastrointestinal structures through the coupling of two ring-shaped components that are inserted into the ends of the segments to be attached.	D
74	Gastrointestinal anastomosis coupler, non-bioabsorbable	An implantable device intended to be used to join and transect excess tissue of gastrointestinal structures through the coupling of two ring-shaped components that are inserted into the ends of the segments to be attached.	C
75	Gastrointestinal catheter/endoscope tracking system	A multicomponent assembly of mains electricity (AC-powered) devices designed for real-time visualization/navigation of a catheter and/or endoscope during insertion in the gastrointestinal tract, by detecting its position/movement within an electromagnetic (EM) field and displaying three-dimensional (3-D) virtual images on a monitoring screen.	B
76	Gastrointestinal endoscopic clip applier	A device intended to be used in combination with a compatible flexible endoscope for the application of a gastrointestinal endoscopic clip(s) [not included] to the mucosal lining of the gastrointestinal (GI) tract for endoscopic marking, haemostasis, tissue approximation, closure of luminal perforations, and/or for treating mucosal/submucosal defects during an endoscopic procedure.	B
77	Gastrointestinal endoscopic clip cutter	A sterile device intended to be used in combination with a generator to remove a gastrointestinal endoscopic clip.	C
78	Gastrointestinal endoscopic clip cutter generator	A portable, mains electricity (AC-powered) device intended to be used in conjunction with a cutter for the endoscopic removal of a gastrointestinal endoscopic clip.	C
79	Gastrointestinal endoscopic clip, long-term	A sterile clip intended to be implanted long-term (>30 days) within the gastrointestinal (GI) tract during an endoscopic procedure for endoscopic marking, haemostasis, tissue approximation, closure of luminal perforations, and/or for treating mucosal/submucosal defects.	C

80	Gastrointestinal endoscopic clip, short-term	A sterile clip intended to be placed short-term (<=30 days) within the gastrointestinal (GI) tract during an endoscopic procedure for endoscopic marking, haemostasis, tissue approximation, closure of luminal perforations, and/or for treating mucosal/submucosal defects.	B
81	Gastrointestinal manometric catheter, electronic	A non-sterile flexible tube with electronic sensors at the distal end intended to be inserted through the nose or rectum into the gastrointestinal (GI) tract to evaluate peristaltic motility anywhere in the GI tract (pharynx, oesophagus, stomach, duodenum, small bowel, colon, and anorectal area) by measuring pressure; it may additionally be intended to measure pH and electrical impedance and contain a lumen.	B
82	Gastrointestinal manometric catheter, non-electronic	A non-sterile, non-electrical flexible tube intended to be inserted through the nose or rectum into the gastrointestinal (GI) tract for measuring pressure to assess peristaltic motility in the GI tract (e.g., oesophagus, stomach) or rectal musculature and anal sphincter functions, typically in the evaluation of GI disorders [e.g., gastro-oesophageal reflux disease (GERD), faecal incontinence].	B
83	Gastrointestinal ostomy tube pocket	A non-sterile, noninvasive pouch designed to be wrapped around the protruding end of a gastrointestinal ostomy tube (e.g., gastrostomy or jejunostomy tube) to hold and support it in order to ensure its stabilization on the patient.	A
84	Gastrojejunostomy tube	A sterile, thin, flexible, hollow cylinder percutaneously inserted into the stomach, typically through puncture of the abdominal wall and stomach after distention of the stomach by endoscopic methods, with an extended portion inserted through the pylorus into the jejunum. It is used to feed a patient who has a physical disability that prevents oral feeding (e.g., a birth defect of the mouth, oesophagus, or stomach, or a neuromuscular condition that affects chewing and swallowing), and to provide drainage/decompression for the stomach when it is necessary to bypass a longstanding obstruction of the stomach outlet into the small intestine.	C
85	Gastro-oesophageal antireflux prosthesis	An implantable device introduced into the gastro-oesophageal sphincter to reduce a sliding hiatal hernia, preventing the reflux of gastric contents into the oesophagus.	C

86	Gastro-oesophageal pH/impedance catheter, non-sterile	A non-sterile flexible tube with electronic sensors at its distal end intended to be inserted through the nose into the oesophagus and stomach to measure pH and/or electrical impedance, typically for the evaluation of gastro-oesophageal reflux disease (GERD), gastric ulcers, or other gastrointestinal conditions.	B
87	Gastro-oesophageal pH/impedance catheter, sterile	A sterile flexible tube with an with an electrical conductor at its distal end intended to be inserted through the nose into the oesophagus and stomach to measure pH and/or electrical impedance, typically for the evaluation of gastro-oesophageal reflux disease (GERD), gastric ulcers, or other gastrointestinal conditions.	B
88	Gastrostomy aspiration system gravity set	A collection of non-sterile devices designed as the external portion of a gastrostomy aspiration system intended to be used post-surgery by the patient after implantation of the stomach tube for the removal of a portion of stomach contents after meals, by aspiration, to achieve portion control and subsequently weight loss in a morbidly obese (bariatric) patient (≥ 18 years).	C
89	Gastrostomy aspiration system stomach tube	A sterile, thin, flexible, hollow cylinder intended to be percutaneously implanted by endoscopic methods into the stomach of a morbidly obese (bariatric) patient (≥ 18 years) for the removal of a portion of stomach contents after meals by aspiration when used with a dedicated gravity kit that is the external portion of a gastrostomy aspiration system.	C
90	Gastrostomy button	A sterile, short, tube that is inserted into the stomach percutaneously to permit long-term enteral feeding.	C
91	Gastrostomy T fastener	A device intended to be inserted into the stomach percutaneously to appose the anterior gastric wall to the anterior abdominal wall, typically to facilitate the insertion of a percutaneous gastrostomy tube or for procedures requiring stabilization/fixation of hollow gastrointestinal (GI) structures.	C
92	Gastrostomy tube Y-piece connector	A sterile connecting device shaped in the form of a "Y" intended for connection to the proximal end of a gastrostomy tube to enable administration of nutrient liquids and/or medication through the gastrostomy tube.	B
93	Gastro-urological director	A slender, rod-like surgical instrument made of metal, typically with groove running along the centre of it distal shaft and/or continuing with an elongated malleable wire loop, that is used to guide other devices or instruments into a selected intracorporeal location during a gastroenterological/urological (GU) procedure.	B

94	Gastro-urological probe	A slender, rod-like, hand-held manual surgical instrument, typically made of flexible metal with a blunt bulbous tip, designed for exploring gastroenterological/urological (GU) structures during a GU procedure.	B
95	Gastro-urological scoop	A heavy, hand-held, manual surgical instrument with a spoon-like, sharp-edged distal end on a long thin shaft that is used to access and scrape tissue from the common hepatic/bile duct system during a gastroenterological/urological (GU) procedure.	B
96	Gravity enema set	A collection of devices intended to be used to deliver an injection of fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine.	A
97	Implantable gastric clamp	A sterile implantable device designed to isolate the lesser curvature segment of the stomach (magenstrasse) to reduce stomach volume and facilitate weight loss in overweight/obese patients through a reduction in food consumption based on an increased sense of satiety (fullness).	C
98	Implantable incontinence-control electrical stimulation system	An assembly of battery-powered devices intended to treat chronic disorders of the pelvis and lower urinary or intestinal tract, typically related to urinary and/or faecal incontinence, through the application of electrical stimuli to the muscles and/or neural tissue of the pelvic floor/bladder.	C
99	Implantable peritoneal catheter holder	A small, sterile, implantable device designed to secure a peritoneal or lumboperitoneal catheter in situ by suturing it to the abdominal fascia at the point of entry/exit.	C
100	Intestinal ostomy bag anti-adhesion device	A non-sterile, noninvasive device intended to be applied to the inner surface of an intestinal ostomy bag to prevent opposing inner walls of the bag from sticking together (anti-pancaking).	A
101	Intestinal ostomy kit	A collection of non-sterile devices intended to be used for attachment/replacement of an intestinal ostomy bag (for collecting intestinal output such as faeces following a colostomy or ileostomy procedure).	A
102	Intestinal splint	A sterile rigid or flexible device intended to be implanted within the abdomen to stabilize a portion of the intestine, or to stabilize and protect an injured portion of the intestine.	C
103	Intestinal stoma shield/support belt, reusable	A non-sterile plate, typically with a waist belt for attachment, intended to be placed over an enteric stoma (surgically-created artificial opening between the intestines and the body surface through which bodily waste is drained) to protect it from harmful external influences (e.g., knocks, friction), to reduce the risk of stomal herniation, or to help maintain	A

		adhesion of the base plate to the skin.	
104	Intestinal stoma shield/support belt, single-use	A non-sterile plate, typically with a waist belt for attachment, intended to be placed over an enteric stoma (surgically-created artificial opening between the intestines and the body surface through which bodily waste is drained) to protect it from harmful external influences (e.g., knocks, friction), to reduce the risk of stomal herniation, or to help maintain adhesion of the base plate to the skin.	A
105	Intraluminal oesophageal retractor	A sterile, hand-held manual surgical instrument intended to be inserted through an orogastric (or nasogastric) tube to mechanically divert the oesophagus away from the site of surgery during electrical treatments of the heart (e.g., cardiac ablation), to facilitate surgical site access and to help prevent injury to the oesophagus.	B
106	Invasive silicone sheet dressing	A sterile, flat stretch of silicone elastomer intended for use as a short-term intra-abdominal dressing following abdominal surgery, when a re-exploration of the wound/abdomen is planned within a thirty day period. It is used to achieve temporary abdominal closure to avoid the complications of an open abdomen.	B
107	Laparoscopic cholangiography catheter/needle	A sterile, flexible, single-lumen tube with a distal needle intended to puncture the neck of the gallbladder (Hartmann's pouch) during laparoscopic cholangiography to allow injection of contrast media.	B
108	Laparoscopic grasping forceps, Non sterile	A sterile, rigid surgical instrument designed to be introduced through a laparoscope primarily for grasping and manipulating tissues during a laparoscopic surgical procedure.	A
109	Laparoscopic grasping forceps, sterile	A rigid surgical instrument designed to be introduced through a laparoscope primarily for grasping and manipulating tissues during a laparoscopic surgical procedure.	B
110	Laparoscopic swab forceps	An instrument designed to grasp a pledget swab at the distal end to obtain cytological specimens and/or to perform blunt dissection during gynaecologic and/or other (e.g., cholecystectomy) laparoscopic procedures.	B

111	Manual enema device	A non-sterile device intended to be used to manually administer fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine through expansion of the lower intestinal tract and physical stimulation of peristalsis.	B
112	Manual enema device, reusable	A device intended to be used to manually administer fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine through expansion of the lower intestinal tract and physical stimulation of peristalsis.	B
113	Manual rectal irrigation system	A portable assembly of manually-operated devices designed to be used by or on a patient to irrigate the rectum with water, typically to provoke the defecation reflex for the evacuation of the bowels to treat/prevent constipation and reduce the risk of faecal incontinence.	B
114	Motorized laparoscopic forceps	A mains electricity (AC-powered) motorized surgical instrument designed for grasping, mobilizing, and suturing tissues/vessels under direct or endoscopic visualization during a surgical procedure.	B
115	Nasoenteral tube	A sterile, thin, flexible, hollow cylinder designed to access the small intestines (duodenum or jejunum) through the nose and nasopharynx for examination (e.g., of intestinal contents), treatment (e.g., decompression, short-term feeding), or other purposes.	B
116	Nasogastric tube holder, intranasal	A non-sterile, non-surgically invasive device intended to be used to secure a nasogastric tube to the nose of a patient to prevent displacement or removal of the tube.	B
117	Nasogastric tube holder, noninvasive, non-sterile	A small, non-sterile, noninvasive device intended to be used to secure a nasogastric tube to prevent displacement or removal of the tube from the patient.	A
118	Nasogastric tube holder, noninvasive, sterile	A small, sterile, noninvasive device intended to be used to secure a nasogastric tube to prevent displacement or removal of the tube from the patient.	A
119	Non-vascular catheter introduction set	A collection of sterile, invasive devices intended to enable percutaneous Seldinger-type introduction of a non-vascular catheter (e.g., drainage catheter) into a body cavity or lumen (e.g., biliary tract, ureter).	B
120	Oesophageal temperature monitor	An electronic device used to monitor the temperature of the oesophagus during surgical ablation of the wall of the left atrium. It typically measures the oesophageal temperature at several adjacent levels, and displays these temperature values simultaneously to help the surgeon avoid the application of heat high enough to form atrial-	B

		oesophageal fistulas.	
121	Paediatric-temperature nasogastric/orogastric tube	A sterile, thin, flexible, hollow cylinder designed as a paediatric or neonatal enteral feeding tube with an integrated temperature sensor that continuously measures oesophageal temperature.	C
122	Partially-implantable abdominal port/catheter	A sterile partially-implantable device intended to provide access to the peritoneal cavity for infusion (e.g., insulin, chemotherapeutic agents).	C
123	Percutaneous biliary biopsy procedure kit	A collection of sterile devices intended to be used to obtain a tissue specimen from within the biliary duct system for histological analysis by a percutaneous endoscopic approach, typically under fluoroscopic visualization.	B
124	Pharyngeal electrical stimulation catheter	A sterile, flexible tubular device intended to deliver pharyngeal electrical stimulation for the treatment of neurogenic dysphagia.	C
125	Powered rectal/colostomy irrigation system	A portable assembly of battery-powered devices intended to be used by, or on a patient, for the controlled introduction of a non-medicated solution (typically water) into the rectum to treat faecal incontinence or constipation (rectal irrigation), and/or for colostomy site irrigation.	B
126	Probiotic oropharyngeal mucosa dressing	A non-sterile substance intended to be applied to the mucosa of the mouth and/or pharynx to facilitate saprophytic microflora colonization within the oral cavity/pharynx, typically following antibiotic therapy, bacterial infection, or injury. It includes probiotic bacteria (e.g., Streptococcus salivarius, Streptococcus oralis) and compounds that create a barrier to facilitate growth of the probiotic bacteria.	C
127	Proctoscope, reusable	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
128	Proctoscope, single-use	A sterile endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
129	Rectal speculum	A hand-held manual surgical instrument intended to be used to expand or stretch the rectal orifice/canal after it is inserted and opened.	B
130	Rectal suction biopsy system	An assembly of disposable and reusable devices designed to obtain a submucosal tissue specimen from the rectum using suction [rectal suction biopsy (RSB)], typically for histopathological analysis [e.g., to help diagnose Hirschsprung's disease (HD)].	B

131	Rectal/colonic lavage support kit	A collection of non-sterile, noninvasive devices intended to be used in conjunction with a rectal and/or colonic irrigation system to support the introduction of an irrigation solution into the rectum/colon.	A
132	Rectoscope, reusable	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
133	Rectoscope, single-use	A sterile endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus.	B
134	Rectoscope/proctoscope handle	A manual device intended to be used as a handle to hold a rectoscope or proctoscope during an examination procedure.	A
135	Rectosocope/proctoscope handle end-cap	A small cap intended to be fitted to the proximal end of the handle of a rectoscope or proctoscope during an examination procedure to provide an airtight seal so that air can be pumped through the scope to inflate the bowel.	A
136	Rigid oesophagoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the oesophagus.	B
137	Rigid sigmoidoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum).	B
138	Robotic electrosurgical instrument, bipolar, single-use	A sterile electrosurgical device intended to be connected directly to the arm of a robotic surgical system to deliver electrosurgical current in a bipolar configuration (i.e., without a return electrode) from a generator directly to tissues for cutting/coagulation/ablation during robotic endoscopic (e.g., laparoscopic, arthroscopic) surgery.	C
139	Robotic surgical retractor	A surgical device intended to be used in conjunction with a robotic surgical system to enable retraction of tissues during a robotic endoscopic procedure.	B
140	Self-propelled flexible video colonoscope	A sterile endoscope with a highly-flexible, self-propelled, inserted portion intended for the visual examination of the entire colon.	B
141	Spring-loaded pneumoperitoneum needle, reusable	A slender, sharply-pointed metal tube designed to introduce or remove gas from the peritoneal cavity as a therapeutic or surgical/radiological procedural method. It is often inserted into the peritoneal cavity for the purpose of insufflation [e.g., with carbon dioxide (CO2)] to establish pneumoperitoneum prior to abdominal endoscopy.	B

142	Spring-loaded pneumoperitoneum needle, single-use	A slender, sharply-pointed metal tube designed to introduce or remove gas from the peritoneal cavity as a therapeutic or surgical/radiological procedural method. It is often inserted into the peritoneal cavity for the purpose of insufflation [e.g., with carbon dioxide (CO2)] to establish pneumoperitoneum prior to abdominal endoscopy.	B
143	Static magnetic anal plug	A non-sterile magnetic device designed to be inserted into the rectum by the user and retained there for a specified period of time (e.g., 1 to 2 hours per day for 10 to 20 days) to help reduce anal haemorrhoids with magnetism.	B
144	Stoma drainage catheter	A sterile flexible tube that is inserted into a stoma (an artificial opening in the body, especially in the abdominal wall, made during a surgical procedure) to drain bodily waste from an internal stoma container; normally directly into the toilet.	B
145	Stoma support implant	A sterile, non-bioabsorbable device intended to be implanted into the abdominal wall during a gastro-urological ostomy procedure to reduce the risk of parastomal hernia by supporting the abdominal wall surrounding the stoma.	C
146	TEM/TEO rectoscope, optical	An endoscope with a rigid inserted portion intended for surgical treatment of the lower part of the bowel during transanal endoscopic microsurgery (TEM) or transanal endoscopic operations (TEO).	B
147	TEM/TEO rectoscope, video	An endoscope with a rigid inserted portion intended for surgical treatment of the lower part of the bowel during transanal endoscopic microsurgery (TEM) or transanal endoscopic operations (TEO).	B
148	Thermal-regulation orogastric tube	A non-sterile, multi-lumen, multi-purpose tube intended for oral introduction into the gastrointestinal (GI) tract for both: 1) enteral feeding/gastric decompression; and 2) thermal regulation of the whole body via thermal transfer across the oesophagus (to lower and alternatively elevate core body temperature).	C
149	Transenteric drainage tube	A sterile non-bioabsorbable tube intended to be endoscopically implanted transmurally between the gastrointestinal (GI) tract and a pancreatic pseudocyst or the biliary tract for drainage.	C
150	Video capsule endoscopy system	An assembly of electronic devices designed for the internal visualization and examination of sections of the gastrointestinal (GI) tract using a non-digestible video capsule after it has been swallowed by a patient.	B

151	Video capsule endoscopy system application software	An individual software application program or group of programs, routines or algorithms that add specific computer assisted display, processing and analysis capabilities to a video capsule endoscopy system.	B
152	Video capsule endoscopy system capsule	A non-sterile, battery-powered, electronic component device of a video capsule endoscopy system designed to be swallowed by a patient for the internal visualization and examination of the gastrointestinal (GI) tract.	B
153	Pancreatic stent	Pancreatic duct stents are often placed in patients who have chronic pancreatitis.	C

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (193) Part III **Date:** 16 MAR 2022

Subject: Classification of medical device pertaining to General Hospital/Orthopaedic Instruments under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix-A

File No. 29/Misc./03/2020-DC (193) Part III
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
Notice

Classification of Medical Devices Pertaining to General Hospital/Orthopaedic Instruments

S. No.	Device Name	Inteded Use	Risk Class
1	Liquid crystal forehead temperature strip	A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence or absence of fever, or to monitor body temperature changes.	B
2	Bed exit monitor, Fall prevention	Intended to be placed under mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.	A
3	Electronic monitor for gravity flow infusion systems	Inteded to electronically monitor the amount of fluid being infused into a patient.	C
4	Electrically powered spinal fluid pressure monitor	Inteded to measure spinal fluid pressure by the use of a transducer which converts spinal fluid pressure into an electrical signal.	B
5	Spinal fluid manometer	A spinal fluid manometer is a device used to measure spinal fluid pressure using needle and graduated column.	B
6	Stand-on patient scale	Intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform.	A
7	Patient scale	A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scaleby placing scale under a bed or chair to weigh both the support and the patient.	A
8	Sterilization process indicator (Biological)	A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization on medical device.	B

9	Sterilization process indicator (Physical/chemical)	A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process on medical device.	B
10	Clinical color change thermometer.	A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature.	A
11	Apgar timer.	The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.	A
12	Hydraulic adjustable hospital bed.	Intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed.	A
13	Manual adjustable hospital bed.	A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed.	A
14	Pediatric medical crib.	Intended for medical purposes for use with a pediatric patient.	B
15	Medical bassinet.	Intended for medical purposes in hospital for use (birth to approximately 5 months of age) in a nursery, labor and delivery unit, or patient room.	B
16	Nonpowered flotation therapy mattress.	A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials, to treat or prevent decubitus ulcers (bed sores).	A
17	Therapeutic medical binder.	Intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place like abdominal, breast and perineal binder.	A
18	Burn sheet.	Inteded to wrap around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants	A
19	Neonatal eye pad.	A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.	A
20	Pressure infusor for an I.V. bag.	Device inteded to inflate and increases the pressure on the I.V. bag to assist the infusion of the fluid	B

21	Intravascular administration set, automated air removal system.	Inteded to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid.	B
22	Patient care reverse isolation chamber.	Device inteded protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality.	B
23	Jet lavage.	A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid.	B
24	Patient lift, Electrcially powered	Inteded to lift and transport patients in hsoptial in the horizontal or other required position from one place to another, as from a bed to a bath.	B
25	Nipple shield.	A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman.	A
26	Lamb feeding nipple.	A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities	A
27	Suction snakebite kit.	Intended for removing venom from the wound.	A
28	Chemical cold pack snakebite kit.	Intended for first-aid treatment of snakebites	D
29	Therapeutic scrotal support.	Intended for medical purposes to support the scrotum (the sac that contains the testicles)	A
30	Cardiopulmonary resuscitation board.	Intended to be placed under a patient to act as a support during cardiopulmonary resuscitation.	A
31	Ultrasonic cleaner for medical instruments.	Intended for cleaning medical instruments by the emission of high frequency soundwaves	B
32	Medical insole.	Intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.	A
33	Ingestible event marker.	An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.	C

34	Remote Medication Management System.	The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional.	B
35	Medical examination light, AC powered or Battery	Intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.	A
36	Skin pressure protectors.	A skin pressure protector is a device intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores)	A
37	Ultraviolet (UV) radiation environmental disinfection device	A medical ultraviolet air purifier is a device intended for medical purposes in hospital/clinic to destroy bacteria in the air by exposure to ultraviolet radiation.	B
38	Ultraviolet (UV) radiation chamber disinfection device.	An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous medical device surfaces by close-controlled UV irradiation.	C
39	Body waste receptacle.	A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.	A
40	Vacuum-powered body fluid suction apparatus.	A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids.	B
41	Washers for body waste receptacles.	A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan.	A
42	Sterilization wrap.	It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used	B
43	Ethylene oxide gas sterilizer.	Intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical devices.	C
44	Dry-heat sterilizer.	A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical devices by means of dry heat.	C

45	Steam sterilizer.	A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical devices by means of pressurized steam.	C
46	Liquid chemical sterilants/high level disinfectants.	A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use.	C
47	Hand-carried stretcher.	A hand-carried stretcher is a device intended to carry patient as an assistance for injury or disability.	A
48	Manual Wheeled stretcher.	A manual wheeled stretcher is a device intended to transport patients in a horizontal position as an assistance to injury or disability.	A
49	Motorised Wheeled stretcher.	A motorised wheeled stretcher is a device intended to transport patients in a horizontal position as an assistance to injury or disability with a motorised mechanism.	B
50	Liquid crystal vein locator.	Inteded to indicate the location of a vein by revealing variations in the surface temperature of the skin.	A
51	Medical washer.	Intended for general medical purposes to clean and dry medical devices, which later undergo sterilization or disinfection before use on patient.	B
52	Medical washer-disinfector.	A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.	B
53	Hydrogen Peroxide Gas Plasma Sterilization System	Intended for sterilization/disinfection of both metal and nonmetal/polymer based medical devices.	C
54	Blood bank centrifuge	Intended to separate blood components of a suspension by application of centrifugal force.	A
55	Environmental chamber for storage of platelet concentrate	A refrigerated environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range	B
56	Blood storage refrigerator	Thsese are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.	B
57	Heat-sealing device	A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.	A

58	Templates	A single use, sterile surgical instrument intended to be used to correctly position an implant. It can be used before making the incision to mark the implant shape, after making the incision, to check the implant position and during the coil pocket creation to check for its size. The product does not include orthopaedic implants.	A
59	X- ray marker for strut	Intended to be used in Six axis correction apparatus with software.	A
60	Clamp	Resuable Handheld Surgical Instrument for clamping tissues or materials or bone. These include Clamp for holding pins.	A
61	Container for orthopaedic cement dispensor	A sterile device in which an orthopaedic cement dispenser is placed to maintain the sterility of the dispenser and its contents when it is taken out of the sterile field to be mixed. The product does not include orthopaedic implants.	A
62	Box Wrench for Nut/Bolt	A minimally invasive, reusable surgical instrument intended to grip, twist or turn nut & bolt.	A
63	Instrument set for external fixation system	The instrument used for external fixation system. These include screw guide, allen key, half pin introducer, jig for fixator, minimally invasive spine surgery access tube, access tube holding handle, hex tightener, retractor blade, light source cable, optic fiber cable.	A

64	Spinal cage system instruments	The spinal cage system instruments are used by surgeon for spinal implants, devices or hardware, uses surgical procedures to implant titanium, titanium-alloy, stainless steel, or non-metallic devices into the spine. The instrument set includes rasp for cervical disc spacer, bone graft compactor, bone tamp for cervical disc spacer, cage support block, cervical distractor pin, cutter for cage, funnel, graft, seat holder for cervical disc spacer, introducer for cervical disc spacer, left angled curette, quick change, quick change for box chisel, spreader, tap handle - quick coupling, threaded inserter for droner peek cage, tlif cage guide, tlif cage holder, tommy bar for cages, trial for droner peek/plif /radial tlif cage, Cervical Distractor, Rasp For Radial Tlif/Plif Cage, Right Angled Curette, Screw Tighter, Pin Introducer For Vertebral Distractor, Plif Cage Holder, Dura, Curette. The system does not include orthopaedic implants.	A
65	Cervical plate system instruments	The Cervical plate system instruments is a comprehensive system of instruments for stabilization of the spine in the cervical regions. The instruments used by surgeon includes pin fixation, plate bender, supporting pin for cervical plate, Screw Tightner for Cervical Plate Screw, Knob Aligner for Cervical Lock Plate, Plate Holder for Cervical Lock Plate, Threaded Pin. The system does not include orthopaedic implants.	A
66	Mesh system instruments	The instrument used by surgeon include mesh holder, mesh pusher, curved mesh pusher, mesh cutter. The instrument is intended to aid surgeon in placing mesh.(Mesh is not apart of the system.). Mesh is used to provide mechanical support for weakened tissues of the pelvic floor.	A
67	Cervical disc spacer instruments for Spine	Intended to be used in cervical disc surgery. The products include Rasp for cervical disc spacer, Graft seat holder for cervical disc spacer, Bone tamp for cervical disc spacer & Lateral mass system & small anatomical system instruments. The product does not include orthopaedic implants.	A

68	Spinal Instrument	The instruments used in spinal surgery. These include Bone Cutter, Bone Nibbler Single / Double Action, Bone Nibbler Single Action, Hijack Punch, Disc Punch, Chisel with Detachable Handle Gouge with fiber handle, Plate holding forcep for C1-C2 spacer, Rounger Right Angle, Sargent Rounger, Rounger Kiliner, Olecrona Rounger, Lacksell Rounger, Kerrison Punch, Rib Rasperactory, Mastroid Retractor, Kochar's Bone hook, Micro cob elevator, Elevator Cobs, Chisel with attached fiber handle, Bone Lever, Micro Curettes, Meatal Curette, Curette, Gauge, Atraumatic Micro Force, Plate holding forcep for C1-C2 spacer, Introducer for C1-C2 spacer.	A
69	Instrument set for Bone Screws & Plates	The instrument set fore bone screw & plates includes Tap, Countersink shaft, Tension device Muller type, handle for quick coupling, holding clip, Dynamic Compression Plate/Limited Contact Dynamic Compression Plate neutral & load guide, bending iron for plates, bending iron for k-wires, Direct measuring device, threaded plate holder , Push pull reduction device, Tension device Muller type, Bending pin, Refractor. The product does not include orthopaedic implants.	A
70	Electronic Drive Instruments & Accessories	The electronic instruments used as orhtopaedic instruemnts. This includes Battery, Battery charger, Tubes for connecting to cuffs, Single cuffs for tourniquet, Double cuffs for tourniquet, High speed Motor control unit, Cutters & Burrs, Straight and Angled Handpieces, Craniotome, Perforator, light source cable, optic fibre cable. The system does not include orthopaedic implants.	A

71	Instrument system for bipolar hip system	The instrument system for bipolar hip system used in surgical procedure includes Advanced Muller Rasp handle for cemented stem, Long scoop for Hip for cemented stem, Rasp for cemented stem, Inserter for cemented stem, Head trail, Tommy bar, Long scoop for Hip for cemented stem, Tommy bar for rasp handle for cemented stem, Trial locating pin for cemented stem, Positioning bar for cemented stem, Head, dismantler for cemented stem, Introducer for cement restrictor, Head trial adaptor, Set of gauges, Ruller for uncemented stem, Rasp handle for uncemented stem, Trial neck for uncemented stem, Rasp for uncemented stem, Repositioning Lever for uncemented stem, Double Curved Gauge for uncemented stem, Proximal Trial Stem for uncemented stem, Gauge for medullary Cavity for uncemented stem, Reduction Lever for uncemented stem, Positioning bar for uncemented stem, Hammer for uncemented stem, Hex wrench for uncemented stem, Distal trial stem for uncemented stem, Proximal trial neck for uncemented stem, Ruller for uncemented stem, Hip head dismenteler for uncemented, Trial adaptor for cemented stem. Implants not included	A
72	Plaster Instruments/Saw	A instrument used to cut or shave or put plaster. The instruments include plaster sawengle type & heavy duty type, plaster bender, plaster spreader, plaster shear.	A
73	Wire tensioner	An orthopaedic, manual hand-held surgical instrument used during orthopaedic surgery to apply an appropriate tension to a wire that is being implanted, usually as part of a system to provide corrective surgery to the spine. The product does not include orthopaedic implants.	A
74	Thick /Thin Guide Pin	The guide pin is to be used facilitate precise placement of a cannulated screw during orthopaedic surgery.	A
75	Depth Gauge	Device intended to aid surgeon in determining the appropriate length retractor blade to use based on surgical site depth through a color-coded system.	A
76	Vice Grip	The product used to hold pliers.	A

77	Bone Tap	A metal surgical instrument designed for cutting internal threads into bone so that the threads facilitate the insertion of bone screws. The screws anchor bone fragments, fixtures and/or other devices to the bone. The product does not include orthopaedic implants.	A
78	Reamer & its attachment	A hand hold instrument used to enlarge. It includes pedicle reamer, reamer for cemented stem, Distal reamer for uncemented stem, adaptors for reamers & Quick Change. The product does not include orthopaedic implants.	A
79	Torque Wrench	The torque wrench is used to tighten the setscrew on the connector assemblies of the implantable pulse generator and extension.	A
80	Pedical Screw Instruments	The instruments include rocker, Tap breaker, Persuader, Sound, Quick Change. These instruments used tio aid surgeon in placing pedical screw in spinal fusion surgery.	A
81	Surgical Probe	It includes curved/straight probe, thorasic probe, Depuy Probe Curved.	A
82	Rod Cutter/Reducer	A reusable surgical instrument used to reduce or seat an implantable rod into the saddle of the implant.	A
83	Alignment Guide	A reusable manual surgical instrument designed to facilitate the correct orientation (alignment) of another medical device or implant during orthopaedic surgery.	A
84	Retractor Holder	A mechanism to which surgical retractors are mounted to, in order for the retractors to hold back tissues.	A
85	Extractor	An instrument, commonly known as a splinter probe, used to aid in the removal of foreign objects from superficial skin tissue. The device is single-use. These include Extractor rod, Extractor hammer, Extractor rod handle, Head extractor for cemented stem, Head extractor.	A
86	Retractor	Handheld surgical device used to hold soft tissues retracted from the field of view. These include Self-Retaining Retractor,	A

87	Bone Curette	A hand held manual surgical instrument used for cutting and excising bone tissue typically during orthopaedic surgery. It is typically a long, slender instrument with a handle at the proximal end and a concave, spoon-like tip which has a sharp edge, at the distal end. The bowl may be open (ring currette) or it may be double-ended, and is used to facilitate the removal of the bone tissue without causing trauma to the surrounding muscles. This is a reusable device.	A
88	Bone Cutter	A surgical instrument used to cut bone to penetrate/separate bone, during orthopaedic surgical procedures.	A
89	Surgical Punch/Bone Punch	A surgical instrument used to punch holes in bone, typically for the purposes of biopsy procedures or for fixation procedures. The instrument can be ring handled, pistol grip or shaft-like in design. Ring handled or pistol grip designs feature extended shafts which terminate in a punch-like or mechanical jaw mechanism at the distal tip. The shaft-like instrument is a hollow tube, sharpened on one end, and is usually used with a trocar.	A
90	Surgical Mallet	A hand held surgical instrument that is used by a surgeon to manually impart a force on another device during surgical intervention.	A
91	Hook	A handheld reusable instrument used to hold tissues or to pull tissues around.	A
92	Dissector	A hand-held surgical instrument, usually spoon shaped or rounded at the working end made of stainless steel, used to separate a soft tissue or body structure from another. It comes in various shapes and sizes but usually has a handle proximally which continues into a shaft as one moves distally. The shaft terminates in a tip which may be pointed or flat, sharp or blunt and angled or straight from the shaft. These include tear drop dissector set & pen field dissector.	A
93	Surgical Spatula	It is reuseable surgical instrument designed to rotate and /or dissect tissues, bone fragments & other instruments.	A

94	Osteotome	A handheld surgical instrument with a flat cutting edge that can be hit with a hammer used to trim bone. These include box osteotome for uncemented stem & Box osteotomy for cemented stem.	A
95	Surgical Elevator	A Handheld Surgical Instrument that is a long flat piece of metal, with a blunt end and an optional hook end, used to lift organs or tissues; with lifting force normally supplied by an assistant.	A
96	Needle Holder	Needle holders intended to secure needles during suturing.	A
97	Scissor	Intended to used for cutting various materials, ie gauze.	A
98	Approximator	A surgical instrument having a shaft-like handle, which tapers as it approaches its distal end. The distal portion of the instrument is curved towards its tip which culminates in a pointed end that is intended to grasp tissue and retract it during a surgical procedure. These include Tibia /femur distal approximator.	A
99	Pliers	The purpose of these instruments is to hold, bend or cut commonly used orthodontic materials such as wires. These include Wire bending pliers, Cerclip plier & locking plier.	A
100	Tamp, Surgical	Inserted into the disc space to pack and fill the disc space with bone graft/bone substitute at the end of surgery. End of shaft is normally impacted with a mallet supplied by the hospital to further pack the bone into the disc space. Not an implantable device.	A
101	Orthopaedic Countersink	The countersinks are bone profilers which are bone-cutting instruments used for bone preparation to enable the placement of gingival part of components during dental procedures in the mouth.	A

102	Wrench	A heavy-duty, surgical instrument with specially designed sturdy handles and gripping jaws (typically parallel) used to grip and hold an object during a surgical intervention. It has a scissors-like design with curved handles and is made of high-grade stainless steel. It is available in various sizes and the jaws (typically broad with serrations) at the working end are activated through a single pivot or a double ratio-lever exchange pivot to provide greater gripping force. This is a reusable device. This include combination wrench.	A
103	Periostic elevator	A sterile, single use dental instrument shaped as a kind of a lever designed to lift, separate, or displace teeth &/or soft tissues during dental procedures.	A
104	Pneumatic Tourniquet & its attachment	The tourniquet used for stopping flow of blood through artery by compression. The attachment includes Consol unit & cuffs.	A
105	Electronically operated Tourniquet Single & Double Cuff Consol	Electronically operated Tourniquet used for stopping flow of blood through artery by compression. This unit include consol.	B
106	Forceps	Forceps are used to grasp, manipulate, compress, pull or join tissue, equipment or supplies. It includes burns for radius, modified burns, martins cartilage forcep, sequestum forcep, reduction forcep, self centering forcep, Fergussons Type Bone Holding forcep, Haygrooves Type Bone- Holding Forcep,Lanes Type Bone – Holding Forcep, Patella with Single Pronge, Patella Double Pronge, Patella with Eye, Rocker Forcep, Plate & Bone Holding Forcep.	A
107	Plaster Knife	A flat-bladed instrument with a cutting edge used to cut or shave plaster.	A
108	Plaster Spreader – Modified & Hanning Type	A manual surgical instrument with specially designed blades used to separate and spread hardened plaster, i.e., that which has already been used to form a cast.	A
109	Surgical Drill & its attachment	The surgical drilling machine that, when rotated at an appropriate speed, will cut into bone creating a hole of the same dimension as the diameter of the bit. The attachment includes drill bit, drill guides, burr & handpiece.	B

110	Surgical Trays	Trays are containers intended to provide a suitable platform for containing many medical/surgical instruments and related items during a clinical procedure. They might in addition be used during reprocessing/sterilization procedures. They are non-invasive, reusable devices.	A
111	Implant Trials	Trials are temporary sizing guides which are used by surgeons to check the size and fit of orthopaedic implants before actual implantation of device. The product does not include orthopaedic implants.	B
112	Computer Assisted Surgery System	Image guided instruments are intended for planning and intraoperative navigation during surgical procedures where the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure such as a long bone can be identified relative to a CT or MR based model or fluroscopy images of the anatomy. The instruments when used in conjunction with the navigational software allo real time tracking with three-dimensional visualization of the surgical field.	B
113	Knee System Instruments	These are surgically invasive instruments which are used manually to assist during total knee arthroplasty. The devices are single use/reusable. The product does not include orthopaedic implants.	B
114	Hip System Instrument	These are surgically invasive instruments which are used manually to assist in the implantation of the femoral or acetabular components in total or hemiarthroplasty. The devices are single use/reusable. The product does not include orthopaedic implants.	B
115	Insertion and removal instruments	Reusable surgical instruments to facilitate the manipulation, implantation and removal of various orthopaedic devices during orthopaedic surgeries.	A

116	Bone cement accessories	Cement Accessories are devices used in conjunction with bone cement to facilitate its handling and penetration into a bone site. Accessories include devices for scrubbing and drying a bone cavity, plugging the cavity to contain the cement in the desired location, hand- or vacuum-mixing the cement, inserting the cement into the prepared cavity, pressurizing the cement to ensure adhesion to the bone, and removing excess soft cement after implantation of prosthetic components. Bone cement/implant not included.	B
117	Sleeves and its attachment	Manual surgical instruments that aid in the placement of bone cuts when preparing site to accept the implant components. These include Sleeve for Block for Half Pin, locking sleeve.	A
118	Arthroscopes	An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.	B
119	Arthroscopic Instruments	These are surgically invasive instruments for manipulating and removing bone and bone fragments. Intended to used in orthoscopic surgical procedure.	B
120	Shaver System	Surgical device intended for the resection of soft and osseous tissues during a surgical procedure.	B
121	Visualization system for arthroscopic and endoscopic procedure	They are used in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of surgical sites.	A
122	Fluid Management System	Irrigation pump with accessories for diagnostic and/or surgical arthroscopic procedures. It pumps medically sterile irrigation fluids through a sterile tube. These fluids are used to distend and irrigate corresponding body cavities to provide space and improve visibility for the surgeon. The products does not include implants.	B
123	Bone Chisel	A single bladed surgical instrument, bevelled on one side, that is intended for use in cutting or contouring bone. Widely used in orthopaedic surgery.	A
124	Pusher	A hand-held dental instrument designed for positioning & adapting metal bands on teeth in orthodontics.	A

125	Bender	A reusable surgical instrument used to bend medical device, typically those for implantation to the appropriate anatomical fit.	A
126	Dilator & accessories	A surgical instrument used for enlarging cavities or openings during surgical procedures. This include dilator incision.	A
127	Surgical Screw Driver	A metal instrument designed to impart force on another instrument. The distal end is shaped to mate with the instrument being driven into some form of tissue. The proximal end is designed to absorb & transmit an impact force.	A
128	Orthopaedic implant impactor	A minimally invasive surgical instrument used in arthroscopy to transmit an impact force on bone and measure the depth of impact.	A
129	Rail Fixation System	The Rail Fixation System consists of series of external fixators intended to be used to stabilize bone segment in a broad range of indications,including fractures, joint fusion, bone transport, lengthening & angular corrections. The system contains rail, Sandwich Plate, Dyna Ring, Bolt For Sandwich Plate, compression-distraction Unit.	B
130	External Ring fixation system	The Ring Fixation System consists of series of external fixators intended to be used to stabilize bone segment in a broad range of indications,including fractures, joint fusion, bone transport, lengthening & angular corrections. The system includes Half Rings 5/8 Ring, Rings With Curved Extremities, Italian Femoral Arches, Arches With Holes, Threaded Rods, Telescopic Rods, Post-Male/ Female, Hinges-Male/ Female/Standard, Long/Short Connection Plates, Connected Plates With Threaded Ends, Twisted/Curved Plates, Bushing Threaded Sockets, Connection Bolts, Nut, Washers, Bolt, Multiple, Wire Fixation Buckle, Blocks for Half Pins, Universal Joint, Rotational and Translational Device, Oblique Support, Set Screw, Foot Rings, Knurling post male. Implants not included	B
131	Six axis correction apparatus with software	The software along with apparatus used to correct multi plane deformity or bone fracture. The system include struts, C/Y plate connector, Labels for strut, clamps, rings, wires & screws.	B

132	Unilateral External Fixation System	A collection of instruments used for the placement of external fixation system into or onto bone that may involve external fixation. The instruments include Rods for holding clamps, Spanners, Compressors, Spanners, Screw Guide.	B
133	Intramedullary Locking Nail Instrument Sets	The Intramedullary locking nail instrument sets includes Awl, Tissue Protector, Nut for coupling bolt, Proximal Jig, Distal Jig, Knob, Proximal Arm for Jig, Coupling bolt, Measuring device, T handle, Universal Spanner, Tommy Bar, Ram, Ram Rod, Jig cover ,Detachable Slide Hammer,F-Tool, Spanner Wrench, Standard Tamp, Screw Tightner,Medullary tube Polyamide.	B
134	Adhesive Plaster B.P.' 88 (Zinc Oxide Adhesive Plaster)	It is intended to secure dressings and for strapping on intact skin.	A
135	Adhesive Tape USP	It is intended to secure dressings and for strapping on intact skin .	A
136	Elasticated Cohesive Bandage	It is intended to secure dressings and for strapping on intact skin .	A
137	Cotton and Rubber Elastic Bandage	It is intended for sprains, strains and painful joints on intact skin.	A
138	Cotton Crepe Bandage	It is intended for sprains, strains and painful joints on intact skin.	A
139	Elastic Adhesive Bandage	It is intended to secure dressings and for strapping on intact skin.	A
140	Extension Plaster –width wise stretchable	It is intended to secure dressings and for strapping on intact skin.	A
141	Microporous surgical tape	It is intended to secure dressings and for strapping on intact skin.	A
142	Orthopedic cast padding	It is intended to protect long prominences under the plaster on intact skin .	A
143	Plaster of Paris Bandage	It is intended for support of fractured body part.	A
144	Tearable adhesive plaster	It is intended to secure dressings and for strapping on intact skin.	A
145	Skin traction kit	It is intended to provide traction for fractured femur.	A
146	Tearable Adhesive Tape	It is intended to secure dressings and for strapping on intact skin.	A

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Date: 03 JUN 2022

File No. 29/Misc./03/2020-DC (181)

Subject: Classification of Medical Device pertaining to Obstetrical and Gynecological under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File No. 29/Misc./03/2020-DC (181)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Obstetrical and Gynecological

Sr. No.	DEVICE NAME	INTENDED USE	Risk Class
1	Abdominal decompression chamber	Non- invasive medical device placed at abdomen to alleviate abdominal pain during pregnancy or delivery.	C
2	Abdominal decompression chamber pump	A dedicated pump used with hood-like device to control and reduce abdominal pressure of a pregnant women.	C
3	Abortion suction system manual aspirator	A non-sterile, manual, syringe-like device to aspirate fluid from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation. Also used for endometrial biopsy.	B
4	Birthing bed/table, powered	Bed used during labor and delivery.	A
5	Cardiotocograph	A device that records fetal heart rate and uterine contraction simultaneously.	C
6	Cardiotocograph transducer	A device that converts birthing contractions to electrical signals and is used together with cardiotocograph (CTG) which displays the signals.	C
7	Cardiotocography telemetric monitoring system	An assembly of devices intended to be used to continuously measure and wirelessly transmit foetal heart rate and uterine contraction signals from a patient to a monitor.	C
8	Cardiotocography telemetric monitoring system receiver	A part of wireless telemeter system. It receives signals from transmitter that senses fetal heart rate and uterine contraction during labor.	C
9	Cardiotocography telemetric monitoring system transmitter	It transmits signals related to fetal heart rate and uterine contractions to the receiver.	C
10	Cervical anaesthesia kit	For providing intercervical nerve block during gynaecological diagnostic tests such as dilation and curettage, small excisional procedures such as endometrial biopsy, or for pain management during labour and/or delivery. This is a single-use device.	B
11	Cervical anaesthesia needle, reusable or single use	A sharp bevel-edged, hollow tubular metal instrument intended to be used to administer anaesthetic agent to function as an intracervical nerve-block.	B
12	Colposcope	Special microscope for examination of female genital organs (e.g., vagina, cervix).	B

13	Contraceptive cervical cap, reusable or single use	Device inserted into the cervix to prevent semen from entering the uterus.	C
14	Contraceptive spermicide	A chemical substance (e.g., nonoxynol-9) intended to be introduced with an applicator or the finger into the vagina before sexual intercourse, to destroy sperm (spermatozoa) to prevent pregnancy.	C
15	Contraceptive sponge	Bubble like device works as a physical barrier to prevent spermatic invasion into uterus.	C
16	Diaphragm pessary	A circular device placed in the vagina prior to intercourse to mechanically prevent conception.	C
17	Endocervical aspirator	A collection of devices designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction.	B
18	Endocervical specimen collection kit, no additive	Sterile devices intended to be used for the collection, preservation, and transport of cellular and/or other material collected from the endocervix for culture, analysis, and/or other investigation	B
19	(a) Endometrial biopsy curette, reusable	Surgical instrument used for the removal of small amounts of endometrial secretions and/or tissue from the uterus for biopsy purposes.	B
	(b) Endometrial biopsy curette, single use/disposable		B
20	Endometrial biopsy kit	For the collection of a tissue sample taken from the lining of the uterus (endometrium).	B
21	Endometrial cytology brush	A brush used to collect mucosal cell for pathological diagnosis during endoscopic examination.	B
22	Fallopian tube biopsy everting-balloon catheter	A sterile device intended to be inserted through a hysteroscope to obtain biopsy samples from a fallopian tube for cytological examination.	B
23	Fallopian tube catheterization kit	A collection of sterile devices for the trans uterine catheterization of the fallopian tubes to inject dye or contrast medium for the evaluation of tubal patency.	B
24	Fallopian tube insufflator	Active invasive device designed to insufflate the Fallopian tubes with a gas [typically carbon dioxide (CO2)] to maintain tubal patency for a procedure.	B
25	Fallopian tube occlusion insert	Contraceptive implantable device implanted into the uterine end of the fallopian tubes to function as a contraceptive by obstructing the natural fallopian tube passage.	D
26	(a) Fixed-diameter cervical dilator, reusable	To dilate the cervical canal with balloon when uterine does not dilate enough due to inertia uteri.	B
	(b) Fixed-diameter cervical dilator, single use/disposable		B

27	Flexible fibreoptic culdoscope	Flexible endoscope for visual examination, diagnosis, and treatment of urinary bladder and urethra.	B
28	Flexible fibreoptic hysteroscope	For the visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
29	Flexible fibreoptic laparoscope	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs	B
30	Flexible fibreoptic mammary ductoscope	For the visual examination and treatment of the mammary duct.	B
31	Flexible fibreoptic salpingoscope	For the visual examination and treatment of the fallopian tubes (oviducts).	B
32	Flexible ultrasound laparoscope	For the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs.	B
33	Flexible video culdoscope	For the visual examination and treatment of the female peritoneal cavity and organs.	B
34	Flexible video hysteroscope	For the visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
35	Flexible video laparoscope	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs.	B
36	Flexible video mammary ductoscope	For the visual examination and treatment of the mammary duct.	B
37	Flexible video salpingoscope	For the visual examination and treatment of the fallopian tubes (oviducts).	B
38	Foetal acoustic stimulator	Uses sound stimuli to assess foetal well-being. This device is used to evaluate the status of the foetus as expressed by, e.g., foetal heart rate changes or foetal acid-base status, in antepartum tests and/or during intrapartum monitoring.	B
39	Foetal bladder shunt	A sterile non-bioabsorbable tubular device implanted in the bladder of a foetus with post-vesicular obstructive uropathy, to decompress the urinary tract for urine to pass from bladder into the amniotic sac, until the defect can be surgically repaired after birth	C
40	Foetal blood sampler	Invasive device to collect fetal blood through uterine cervix.	B
41	Foetal cardiac monitor	Active device designed to detect, measure, and display foetal heart activity during the perinatal period	C
42	Foetal pleuro-amniotic catheter	Sterile implantable device used to continuously drain fetal pleural effusion to maternal amniotic cavity.	C
43	Foetal scalp electrode, clip	Placed directly on the scalp of the fetus in the uterus to monitor fetal vital signs.	C
44	Foetal stethoscope	Mechanical hearing device used to listen to fetal heartbeat.	A
45	Foetal vacuum extraction cup, reusable or single use	A device used to extract the head of the fetus with a vacuum cup.	B

46	Foetal vacuum extraction system monitor	A battery-powered vacuum measuring device that is connected via tubing to the suction line of a foetal vacuum extracting cup, to measure and record data related to a vacuum-assisted delivery such as level of vacuum applied, the number and duration of pulls, and number of pop-offs.	B
47	Foetal vacuum extraction system, manual, reusable or single use	To facilitate the delivery of a foetus during vaginal childbirth or Caesarean.	B
48	Foetal vacuum extraction system, pneumatic	To facilitate the delivery of a foetus during vaginal childbirth or Caesarean.	B
49	Foetal/maternal multiple physiological parameter simulation kit	To imitate a variety of physiological parameters and conditions (both foetal and maternal) expressed during pregnancy in order to test and calibrate foetal and patient monitoring and recording equipment, check patient cable continuity, or train healthcare providers.	B
50	Foetal/maternal multiple physiological parameter simulator	To imitate a variety of physiological parameters and conditions (both foetal and maternal) expressed during pregnancy in order to test and calibrate foetal and patient monitoring and recording equipment, check patient cable continuity, or train healthcare providers.	B
51	Gynaecological bib	A piece of cloth worn by the patient.	A
52	Gynaecological examination/treatment table	To support a woman's body in the appropriate positions during gynaecological examinations.	A
53	Gynaecological operating table top	A component of a modular operating table designed as a detachable table top constructed for gynaecological surgical procedures.	A
54	Gynaecological operating table, electrohydraulic or electromechanical or hydraulic	Active device designed to support a patient during gynaecological surgical procedures	A
55	(a) Gynaecological scissors, reusable	To cut tissues during a gynaecological surgical procedure; it is not intended for obstetric use.	B
	(b) Gynaecological scissors, single use/disposable		B
56	Gynaecological surgical microscope	To improve visualization of anatomical structures via transmitted light during gynaecological surgery (e.g., on the fallopian tubes).	A
57	Heel stirrup	A device used during a medical/surgical procedure to steadily hold a patient's foot (feet) by cradling the heel or the whole foot.	A
58	Hysteroscopic insufflator	A device that sends the gas into the fallopian tube to maintain the patency of the tubes.	B
59	Hysteroscopic irrigation/insufflation system	Used during endoscopic procedures of the uterus to distend (expand by pressure) the uterus by filling the uterine cavity with a liquid to improve visualization and enlarge the surgical field. It also circulates the fluid to provide irrigation that will remove tissue/debris from the site.	B

60	(a) Intrauterine cannula, reusable	To aspirate fluid/material from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation; it may also be intended for endometrial biopsy.	B
	(b) Intrauterine cannula, single use/disposable		B
61	Intrauterine haemostatic balloon catheter	A sterile, flexible tube with an inflatable balloon inserted into the uterus and distended with a medium (e.g., sterile water, medical air or other appropriate gas) to reduce postpartum bleeding with pressure.	B
62	Intrauterine haemostatic suction catheter	Inserted into the uterus to reduce postpartum bleeding through aspiration of blood/debris and induction of uterine contractions.	B
63	Intrauterine imaging medium catheter	Intrauterine injection of an opaque tracer medium, to facilitate radiography of the fallopian tubes/uterus.	B
64	Intrauterine imaging medium catheterization kit	Sterile devices intended for the intrauterine injection of an opaque tracer medium, to facilitate radiography of the fallopian tubes/uterus.	B
65	(a) Laparoscope laser coupler	To connect the laparoscope to the laser or the laser arm for laparoscopic laser treatment.	B
	(b) Laparoscope laser adaptor		A
66	Laparoscope system	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs (laparoscopy).	B
67	Laparoscope system, reusable or single use	For the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs (laparoscopy).	B
68	Manual expandable cervical dilator	To dilate the cervical canal with balloon when uterine does not dilate enough due to inertia uteri.	B
69	Mechanical foetal heart simulator	To imitate a foetal heart (e.g., foetal heart ultrasound signals) when used in combination with a foetal/maternal multiple physiological parameter simulator in order to test foetal monitoring and recording equipment [e.g., cardiotocograph (CTG)], check patient cable continuity, or to train healthcare providers.	B
70	Motorized laparoscopic forceps	Active surgical instrument designed for grasping, mobilizing, and suturing tissues/vessels under direct or endoscopic visualization during a surgical procedure.	B
71	Papanicolaou smear kit or Endometrial sampling kit	Used to collect and prepare pap smears samples in a medical institute.	B
72	Pelvic examination kit	For performing pelvic examination	B
73	Pelvimeter	A measuring device used to determine the pelvic dimensions.	B
74	Pelviscope	An endoscope used for visual examination and diagnosis of pelvis.	B
75	Perineal warmer	it is useful for pain relief in the vulva after episiotomy.	B
76	Perineometer	To determine perineal muscle strength through resistance to spontaneous contraction of perineal muscle. Also used to diagnose and treat urinary incontinence and sexual dysfunction through movement.	B

77	Pudendal anaesthesia kit	A collection of sterile devices designed to deliver anaesthetic agent to the external genitalia of humans.	B
78	Resectoscope	An endoscope used for visual examination, diagnosis and treatment, especially for resection of tissues.	B
79	Rigid culdoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the female peritoneal cavity and organs.	B
80	Rigid fibreoptic hysteroscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
81	Rigid mammary ductoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the mammary duct	B
82	Rigid optical laparoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs.	B
83	Rigid salpingoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the fallopian tubes (oviducts)	B
84	Rigid ultrasound laparoscope	An endoscope with a rigid inserted portion, combined with an ultrasound probe, intended for the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs	B
85	Rigid video hysteroscope	Active device intended to allow visual examination and treatment of the canal of the cervix and the uterine cavity (uterus).	B
86	Rigid video laparoscope	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the abdominal/retroperitoneal cavity and its organs	B
87	(a) Suprapubic needle, surgical, reusable	Percutaneously puncture the lower abdominal wall to provide suprapubic access for surgical repair.	B
	(b) Suprapubic needle, surgical, single use/ disposable		B
88	Umbilical ligator	Surgical device used for umbilical cord ligation.	A
89	Uterine injector	Used to inject liquid, drug, or other substance into uterus. It is a reusable device.	B
90	Uterine manipulator cervical cup/transilluminator	Allow manipulation of the uterus under suction whilst preventing laparoscopic insufflation gas from escaping from the cervix (during hysterectomy).	B
91	(a) Uterine manipulator, reusable	Surgical instrument designed to mechanically manipulate the position of the uterus during a gynaecological intervention	B
	(b) Uterine manipulator, single use/disposable		B

92	Uterine packer	A hand-held, surgical instrument used to introduce dressings into the uterus or vagina. This is a reusable device.	A
93	(a) Uterine probe, reusable	For exploring the uterus during a surgical procedure. Used as a component of a uterine manipulator	B
	(b) Uterine probe, single use/disposable		B
94	Uterus-supporting pessary	Inserted into the vagina to hold the uterus in place.	B
95	Vaginal applicator, reusable or single use	A device designed to apply medication to the vagina.	A
96	(a) Vaginal dilator, reusable	Inserted into the vagina to dilate a narrow vaginal opening due to congenital defect. Can be used during examination, treatment or surgical procedure.	B
	(b) Vaginal dilator, single use/ disposable		B
97	Vaginal douche, reusable or single use	To deliver a liquid (usually solution) directly into the vaginal cavity for hygienic purpose as a douche.	B
98	Vaginometer	A device that measures the length and diameter of vagina.	A
99	Vaginoscope	For paediatric vaginal examination. To search foreign matter or bleeding site.	B
100	Viscera retention paddle or Visceral retainer	Used to hold an organ at proper position (i.e., viscera) while the surgeon performs a suturing procedure (typically internal wound closure). It is also implanted into a surgical site temporarily.	B
101	Breast transilluminator	Active device transmitted through the female breast to visualize translucent tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities.	C
102	Amniotic membrane perforator, reusable	A surgical instrument used to rupture the amniotic membrane to assist in childbirth, without causing injury to the mother or foetus	A
103	Amniotome, reusable	A surgical instrument used to rupture the amniotic membrane to assist in childbirth, without causing injury to the mother or foetus	B
104	Bladder-supporting pessary	inserted into the vagina to facilitate management of female urinary incontinence and/or to reduce bladder prolapse.	B
105	Catheter-tip transducer, pressure	A device intended to be incorporated into the distal end of a catheter (not included) to measure pressure.	B
106	Foetal Doppler system	Active non-invasive device to detect foetal heart beats using ultrasound/Doppler technology.	C
107	Foetal Doppler system probe	Placed on the surface of a pregnant woman's abdomen to detect foetal heart beats using ultrasonic/Doppler technology.	C
108	Preservation medium for human semen	It is intended for cryopreservation of human semen for later use in Assisted Reproductive procedure. It may include medicinal and biological components like glycerol, gentamicin, Test Yolk Buffer (TYB),etc.	C
109	Sperm cryopreservation medium	It is intended for use in Assisted Reproductive procedure involving the cryopreservation and storage of semen.	C

110	Vitrification freezing kit	It is intended for use in Assisted Reproductive procedure for vitrification and storage of human oocytes (MII), Pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. It may include medicinal and protein supplements like Gentamicin, Dextran Serum Supplement (DSS), etc.	C
111	Vitrification Thawing/Warming kit	Intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos that have been vitrified using vitrification freeze kit.It may include medicinal and protein supplements like Gentamicin, Dextran Serum Supplement (DSS), etc.	C
112	Handling medium	Intended for use in Assited reproductive procedure which involves manipulation of gametes or embryos. Specially, it is indicated for use as an oocyte retrival medium during ovarian follicle aspiration procedure, washing sperm prior to IVF and ICSI (Intra Cytoplasmic sperm injection) fertilization procedures, and for transport of the embryo to the utreus during embryo transfer procedure. It may include medicinal and protein supplements like Gentamicin, Human Serum Albumin (HSA), etc.	C
113	Gamete and embryo retrieval, storage and transfer medium	Used in Assisted reproductive procedure which includes retrieval, culture, transport,storage, handling, and transfer of human gametes and embryos by creating a physiological environment. It may include buffer solution and medicinal substance like Gentamicin, etc.	C
114	Hyaluronidase solution	Intended for use in removing cumulus cells surrounding oocytes (denudation) in preparation for ICSI (Intra cytoplasmic sperm injection) or other Assisted reproductive procedures. It is a enzymatic solution containing of bovine derived hyaluronidase in a HEPES (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) buffered HTF (Human Tubal Fluid) medium supplemented with therapeutic grade human serum albumin and gentamicin sulfate.	C
115	Polyvinylpyrrolidone (PVP) Solution	Used in Assisted reproductive procedure which include human gamete and embryo manipulation. It uses PVP solution for immobilizing sperm for ICSI (Intra cytoplasmic sperm injection) procedures.This solution may include protein supplement like Human Serum Albumin (HSA), etc.	C
116	Sperm Separation Medium	It is intended for separation of the motile fraction of sperm from seminal fluid. It works on the principle of isopycnic separation.	B
117	Sperm processing media	Designed to maintain sperm quality on the table top without CO2 incubation. This procedure includes use of this medium for sperm washing by supporting all steps of sperm preparation prior to fertilization. It may contains protien supplements like human serum albumin (HSA), bovine serum albumin, etc.	C
118	Water for Assisted Reproductive Technologies	Intended for use in ART Laboratories procedure requiring a non-pyrogenic high quality pure grade of water.	B
119	In Vitro embryo Culture medium, through day 5/6 of development	It is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. It is used as a culture medium for human gametes and embryos from fertilization through day 5/6 of development. It may include medicinal substance like Gentamicin and protein supplement like Human serum Albumin (HSA), etc.	C

120	In Vitro embryo culture medium, through day 3 of development	This medium is intended for use in assisted reproductive procedures which include human gamete and embryo manipulation. It is used as a culture medium through day 3 of development. It may be used as a stand-alone medium, or as the first stage of a sequential medium protocol. It may include medicinal substance like Gentamicin, etc.	C
121	Protein supplement for in vitro embryo culture	For use in assisted reproductive procedures which include gamete and embryo manipulation, as a supplement for culture media. It may include protein supplement like Human Serum Albumin (HSA), Synthetic Serum Substitute (SSS), Dextran Serum Supplement (DSS), etc. Not for use as an injectable product.	B
122	Oil for embryo culture	It is used as an overlay to cover small volumes of culture media during human embryo and gamete manipulation to prevent evaporation of culture media.	B
123	Menstrual Cup	Placed in the vagina to collect blood and cellular debris discharges during menstruation and discharges outside of the monthly menses.	B

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (160) **Date:** 24 AUG 2022

Subject: Classification of medical devicepertaining to Rehabilitation under the provisions ofMedical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devicesbased on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix-A

File No. 29/Misc./03/2020-DC (160)
Drugs Controller General (India)
DirectorateGeneralofHealthServices
FDABhawan,KotlaRoad,New Delhi

Notice

ClassificationofMedicalDevicesPertainingto Rehabilitation

S.No	Name of the Medical Device	Intended use	Classification India as per First Schedule part-1 MDR 2017
1	Acupressure calf band	Intended to wear around the calf to apply pressure to an acupressure point to relieve low back pain, including sciatica and piriformis syndrome. A Non powered belt like device.	ClassA
2	Arthritis TENS system	Intended to be used as adjunctive therapy in reducing the level of pain and stiffness associated with rheumatoid arthritis or osteoarthritis by electrically stimulating peripheral nerves across the skin (transcutaneous).	ClassB
3	Back/leg/chest dynamometer, electronic	Powered device intended to assess neuromuscular function by measuring the force or power exerted by the back, chest, and/or leg muscles during flexion.	ClassB
4	Back/leg/chest dynamometer, mechanical	Non powered device intended to assess neuromuscular function by measuring the force or power exerted by the back, chest, and/or leg muscles during flexion.	ClassA
5	Balance-training tongue electrical stimulation system	Intended to provide biofeedback for training of balance by sensing body movements and subsequently producing signals which are translated into electrical stimuli applied to the tongue, enabling a patient to correlate electrotactile stimulation with their head and body position during exercise sessions.	ClassB
6	Bed/chair electric massager	Intended to provide therapeutic massage to the occupant of a bed or chair for the treatment of body aches and pains.	ClassB
7	Bicycle ergometer	Intended to be used to provide a quantitative measurement of the rate at which work (energy) is performed by a muscle or group of muscles under controlled conditions.	ClassA

8	Bladder-emptying vibratory stimulator	Intended to initiate urination and facilitate complete bladder emptying through application of small mechanical vibrations to the lower abdomen to promote urethral sphincter relaxation.	ClassB
9	Blue/red/infrared phototherapy lamp	Intended to emit blue light, red light, and infrared radiation (heating effect) for phototherapy treatment of mild skin disorders (e.g., mild acne), superficial skin wounds, and musculoskeletal symptoms (e.g., pain, spasm, stiffness).	ClassA
10	Circulating-fluid thermal therapy system	Intended to be used to pump heated and/or cooled fluid (e.g., water) through externally applied packs for localized hot and/or cold therapy to help treat a variety of adverse conditions resulting from musculoskeletal injury (e.g., pain, swelling, inflammation).	ClassB
11	Cold compression therapy cervical spine collar	Intended to facilitate, through cooling and compression, the treatment of a variety of conditions resulting from injury/surgery to the neck region (e.g., inflammation, stiffness, whiplash).	ClassA
12	Cold/cool therapy gel	intended for localized topical skin application to provide a cooling effect for underlying muscles/joints to reduce pain and swelling.	ClassA
13	Cold-air therapy unit	Intended to reduce localized pain/inflammation, and/or to reduce thermal skin damage by applying cold stream of air during dermatological laser treatments.	ClassB
14	Core-body mechanical weight exerciser	Intended to enable a patient with a lumbar spine injury to perform controlled extension, contraction, and/or twisting movements of the lumbar/thoracic spine back region and the abdomen, for testing and rehabilitation.	ClassA
15	Deep-tissue electromagnetic stimulation system	Intended to apply an electromagnetic (EM) field to body tissues to: 1) treat musculoskeletal disorders (e.g., osteoarthritis, osteoporosis); 2) treat body pain (musculoskeletal, postsurgical); and/or 3) help facilitate soft and hard tissue wound/injury healing, with no production of a therapeutic deep heat.	ClassB
16	Electromechanical orthopaedic extracorporeal shock wave therapy system	Intended to provide electromechanical orthopaedic extracorporeal shock wave therapy (OEST) to treat musculoskeletal disorders.	ClassC

17	Electronic goniometer/kinesiology sensor	Intended to evaluate a patient's range of motion/movement of individual joints/limbs/spine; it is used in a clinical setting typically before/after a medical/surgical intervention, or to assess degree of physical fitness.	ClassB
18	Exothermic heat therapy pack	Intended to be applied to the body surface, sometimes with pressure, to provide heat therapy to reduce muscle spasms and cramps and/or for joint and muscle stiffness and pain.	ClassA
19	Foot sensorimotor therapy mechanical neurostimulator	Intended to provide non-invasive peripheral neurostimulation to the feet for improving somatosensory integration, typically for reducing motor impairments and balance disturbances in patients with neurological or neurodegenerative disorders (e.g., Parkinson's disease).	ClassC
20	Gait analysis system	Intended to be used to study walking or running patterns.	ClassA
21	Hand dynamometer/pinch meter, electronic	Electronic device intended to assess neuromuscular function by measuring the force or power exerted by the muscles of the hand/forearm to squeeze/pinch an object.	ClassB
22	Hand dynamometer/pinch meter, mechanical	Mechanical device intended to assess neuromuscular function by measuring the force or power exerted by the muscles of the hand/forearm to squeeze/pinch an object.	ClassA
23	Hydrotherapy treadmill	Powered device intended for use in partially immersed in water, e.g., in a hydrotherapy tank, to provide additional resistance to the treadmill walking exercise without increasing the impact and/or stress on the patient's joints.	ClassA
24	Interferential electrical stimulation system	Intended to stimulate peripheral nerves through the transcutaneous application of two currents of slightly different frequencies that cross-over/interfere, producing a beating frequency at the treatment point.	ClassC
25	Manual goniometer	Non powered device intended to be used in a clinical setting to measure the range of motion of the limb of a patient by measuring the angle of movement achieved at the joint.	ClassA

26	Medium-wave diathermy treatment system	Intended to produce a therapeutic deep heat within specific volumes of the body through the transcutaneous transmission of electromagnetic (EM) energy in the radio-frequency (RF) bands of 0.5 MHz to 1 MHz	ClassB
27	Microwave diathermy treatment system	Intended to produce a therapeutic heat 1 to 2 cm below the skin within specific volumes of the body through the transcutaneous transmission of high frequency electromagnetic (EM) energy, typically 2,450 megahertz (MHz) [microwave], to promote tissue healing and pain relief.	ClassB
28	Musculoskeletal infrared phototherapy unit,	Intended to provide a source of infrared (IR) heat for localized treatment of musculoskeletal pain/injury (e.g., muscle pain, sports injury, rheumatism) and to improve blood circulation in the treated areas to facilitate healing.	ClassB
29	Musculoskeletal intense therapeutic ultrasound system	Intended to produce and deliver intense therapeutic ultrasound (ITU) waves through the skin to create ablative lesions in subcutaneous soft tissues (e.g., muscles, tendons).	ClassC
30	Musculoskeletal/ physical therapy laser	Intended to provide noninvasive laser therapy [e.g., infrared phototherapy, low-level laser therapy (LLLT)] for localized treatment of musculoskeletal conditions (e.g., muscle pain, sports injury, disorders of the joints and soft/connective tissues), improving blood circulation in the treated areas to facilitate healing, or for non-needle acupuncture.	ClassC
31	Parallel bar exerciser,	Intended to assist users in maintaining good walking posture, particularly a person with a disability, a paraplegic, or a patient who has suffered a stroke and is learning to walk.	ClassA
32	Physical therapy massager	Electrically powered device intended to provide therapeutic massage to a larger area than hand-held massaging devices.	ClassB
33	Physical therapy paraffin wax bath	Intended to be filled with liquid paraffin wax for physical therapy.	ClassB
34	Physical therapy steam bath	Intended to apply hot steam as a physical therapy to a patient.	ClassB
35	Pulsed signal therapy system	Intended to regenerate damaged cartilage, particularly by stimulating the production of collagen types that are present in healthy cartilage.	ClassC

36	Short-wave diathermy treatment system	Intended to provide a therapeutic deep heat within specific volumes of the body through the transcutaneous transmission of electromagnetic (EM) energy in the radio-frequency (RF) bands of 13 MHz to 27.12 MHz	ClassC
37	Telemetric diagnostic spirometer	It is a Battery powered portable device Intended to measure several or all respiratory-gas volume and flow parameters needed to evaluate basic pulmonary function [e.g., vital capacity (VC), peak expiratory flow (PEF), forced expiratory volume (FEV), and forced expiratory flow (FEF)], and to transmit the pulmonary function data via a communication device to a healthcare professional(s) at a remote server.	ClassB
38	Therapeutic nuclear magnetic resonance system	Intended to influence cellular metabolism using nuclear magnetic resonance (NMR) for the treatment of degenerate and pathological changes to the movement/support profiles of a patient's body, in particular diseased skeletal joints, bones, and surrounding muscle tissue (e.g., cervical and lumbar spine, shoulders, elbows, hands, hips, knees, feet).	ClassC
39	Silicone Prosthetic Ear	A silicone prosthetic ear which adheres to the skin using safe, biocompatible glue is a reconstructive option for patients born with microtia and other birth differences such as Treacher Collins or Goldenhar syndrome; as well as those who have suffered traumatic injury or undergone cancer resection surgery.	Class A
40	Silicone Prosthetic Nose	Silicone prosthetic nose is used to restore normal contour and improve function for patients who have experienced partial or total loss of their nose to traumatic injury, disease or due to surgical removal of the nose (rhinectomy).	Class A
41	External asembled lower limb prosthesis	An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following:	Class A

		Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.	
42	External limb prosthesis socket liner	The prosthetic liner acts as an interface that goes between a person's skin and his or her prosthetic. In short, it's a barrier – one that is applied to the skin before the prosthesis to protect the wearer's skin while enhancing comfort and maintaining a more consistent fit.	Class A
43	Finger/thumb prosthesis	An artificial substitute for a missing finger or thumb.	Class A
44	Upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components.	A upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.	Class B
45	Powered lower extremity exoskeleton	A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.	Class B
46	TruncalOrthosis	A truncalorthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of	Class A

		truncalorthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.	
47	Prosthesis External Arm	External prosthesis for upper limb distal to shoulder joint. The device is intended to be used by patients with upper limb loss or deficiency. Prosthesis may include limb components, socket, frame, covering and accessories to enable functional use of the device.	Class A
48	Congenital hip dislocation abduction splint	A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).	Class A
49	Denis Brown splint	A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.	Class A
50	Arm sling	An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.	Class A
51	Crutches	Crutches helps to transfer load from the legs to the upper body. This is useful for people who cannot use their legs to fully support the weight of their body, due to temporary or permanent disabilities.	Class A
52	Power Knee	The Power Knee is a motor-powered microprocessor knee. It provides active assistance while walking on level-ground, climbing and descending ramps or stairs and when standing up. Power Knee enables amputees to maintain and regain mobility and participate in the daily activities.	Class B

53	Abdominal Support	It holds abdominal muscles together to relieve pain. Increase circulation at your surgical site to promote healing and decrease swelling. Make physical activity more comfortable.	Class A
54	Myoelectric forequarter-amputation prosthesis	The complete control system is to be used exclusively for external prosthetic fitting of the upper limbs.	Class A
55	Stocking, medical support	Limb support shaped as a stocking unit that is worn on the upper or lower extremity to support, correct, prevent deformity, or to align body structures for functional improvement.	Class A
56	Back Support/Brace	A back brace prevents unnecessary movements that further damage the back. This helps align your spine and strengthen your back muscles. Patients back can heal and back pain will decrease.	Class A
57	Prosthetic and orthotic accessory	A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.	Class A
58	External limb orthotic component	An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.	Class A
59	External limb prosthetic component	An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis.	Class A

		Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.	
60	Prosthesis, external, arm, component, hand, external powered, myopotential	A controller for prosthetic terminal devices that enables grip and mode switching using passive RFID tags.	Class A

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2022-DC (228) **Date:** 09 SEP 2022

Subject: Classification of non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

Classification of non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures placed at Appendix A subjected to the followings:

1. General intended use given these devices is for guidance. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

VGS

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

F. No. 29/Misc./03/2022-DC (228)
Government of India
Directorate General of Health Services
Ministry of Health & Family Welfare
Central Drugs Standard Control Organisation
(Medical Devices Division)

FDA Bhawan, Kotla Road,
New Delhi- 110002

Notice

Classification of Medical Devices pertaining to non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures

'Non-Sterile and Invasive Surgical Instruments' are commonly intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be used after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.

S. No.	Name of the Medical Devices	Intended Use	Risk Classification
1	Cutting and Dissecting Surgical instruments	These are transient use invasive surgical instruments, usually have sharp edges or tips to cut through skin, tissue, and suture material. Intended to cut and dissect tissue to explore irregular growths and to remove dangerous or damaged tissue. Also used for cutting sutures.	A
2	Clamping and Occluding Surgical instruments	These are transient use invasive surgical instruments, intended for use in many surgical procedures for compressing blood vessels or hollow organs. In order to prevent their contents from leaking or control bleeding or Occlude. They are designed straight, curved or angled, or ratcheted and have a variety of inner jaw patterns.	A

3	Retracting and Exposing Surgical instruments	These are transient use invasive surgical instruments, intended to hold back, or retract organs and tissue, or other article to have access to the operative area during surgical procedure. They spread open the skin, ribs and other tissues; and are also used separate the edges of a surgical incision.	A
4	Grasping and Holding Surgical instruments	These transient use invasive surgical instruments are intended to grasp and hold tissue or blood vessels that may be in the way during a surgical procedure. Designed serrated or non-serrated at the tip.	A

Note for clarification:

1. “transient use” means a device intended for continuous use for less than sixty minutes.
2. “invasive device” means a device which, in whole or part, penetrates inside the body, either through a body orifice or through the surface of the body.

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

10 OCT 2022

File No. 29/Misc./03/2020-DC (140) Part-5 (a) **Date:**

Subject: Classification of Medical Device pertaining to Dental under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File No. 29/Misc./03/2020-DC (140) Part-5 (a)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Dental

S. No.	Medical Device Name	Intended Use	Risk Class
1	Dental impression material	This material is primarily used to take an oral impression.	A
2	Dental collar/crown scissors	Scissors use to cut delicate tissue to removing sutures to performing precision procedures.	A
3	Dental excavator, reusable	It is a device intended to cutting, clean out and shape a carious cavity before filling it.	A
4	Dental excavator, single-use	It is a single use device intended to cutting, clean out and shape a carious cavity before filling it.	A
5	Dappen dish, reusable	It is a small bowls used to mix and hold dental materials. These dishes can be disposable or reusable	A
6	Dappen dish, single-use	A small, shallow concave vessel used to knead and hold dental materials.	A
7	Dental examination kit	Intended as a kits for dental examination.	A
8	Dental crown, polymer	A device made entirely of polymer-based material with or without fibre reinforcement, and created for a specific patient, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
9	Dental crown/bridge resin, temporary	A material used to manufacture crowns and bridges.	B
10	Dental crown/bridge, temporary	Intended to make a temporary crown or bridge prosthesis for use until a permanent restoration is fabricated.	B
11	Dental material mixing surface, reusable	A dental instrument slab or tray used as a surface to mix dental materials.	A
12	Dental material mixing surface, single-use	It has pad or tray used to knead or mix dental material (impression material, cement, etc).	A
13	Dental spatula, reusable	A dental instrument used to mix dental materials. Some are equipped with an injection function.	A
14	Dental spatula, single-use	A spatula-shaped device used to knead or mix dental material (impression material, cement, etc).	A
15	Dental crown, metal/ceramic	A device made of a combination of metal and tooth-coloured ceramic, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
16	Dental crown, metal/polymer	A device made of metal, veneered with a polymer-based, tooth-coloured material, and created for a specific patient, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B

17	Dental impression material kit, reusable	Devices and materials used to take the impression.	A
18	Dental impression material kit, single-use	A collection of non-sterile devices designed to obtain a negative imprint of the teeth. The kit typically includes dental impression materials and a dental impression tray(s); This is a single-use device.	A
19	Dental impression material mixer	An electric device used to mix impression materials immediately before use at the chair side.	A
20	Dental impression material syringe	This dental injection syringe is used to inject the impression material onto the impression tray.	A
21	Dental impression tray material	A material intended to be used to create a custom impression tray intended for filling with dental impression materials; it is not intended for the fabrication of a patient-worn dental appliance. The material is used in cases in which a preformed impression tray is not suitable.	A
22	Dental impression tray, reusable	A impression tray is a metal or plastic device intended to hold impression material, to make an impression of a patient's teeth to reproduce the structure of a patient's teeth.	A
23	Dental polishing brush	A rotary dental brush intended for cleaning and polishing by a dental hygienist or a dentist.	A
24	Dental bone particle collector	A device used to collect bone debris generated by drilling, etc. during oral surgery.	B
25	Dental bone matrix implant, animal-derived	A sterile bio absorbable device made primarily of animal-derived bone or dentin matrix (e.g., bovine, porcine) implanted into the body to provide osteoconductive bone-tissue scaffolds to replace maxillofacial and/or mandibular bone lost through trauma or dental surgery. It is used to fill bone cavities and defects and contains pores that promote the ingrowth of endogenous bone for skeletal reconstruction and/or augmentation.	C
26	Dental suction system	It evacuate solids, liquids, aerosols and gases from the oral cavity and immediate surrounding area for the purpose of improving operating effectiveness and efficiency during oral treatment procedures and limiting the contamination of the immediate environment.	B
27	Dental suction system cannula, reusable	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity. This device is reusable after sterilization.	A
28	Dental suction system cannula, single-use	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity.	A
29	Carboxymethylcellulose sodium denture adhesive	An adhesive compound composed of carboxymethylcellulose sodium (usually 40 to 100%) used to stabilize a removable prosthesis in the mouth, particularly a denture, by adhering the prosthesis to the oral mucosa. The compound is typically applied to the base of a denture before it is inserted in the mouth.	B

30	Carboxymethylcellulose sodium/polymer denture adhesive, zinc-free	An adhesive compound intended to be used to stabilize a removable prosthesis in the mouth, particularly a denture, by adhering the prosthesis to the oral mucosa. The compound is typically applied to the base of a denture before it is inserted in the mouth.	B
31	Dental amalgam	A dental restorative material used primarily to fill tooth cavities, prepared by mixing liquid mercury (Hg) with an alloy of fine particles, composed mainly of silver (Ag), tin (Sn) and copper (Cu).	B
32	Dental suction system fluid-separation unit	A separator used in the oral cavity. Used for the separation of fluids (saliva, blood) from gases to avoid liquids from entering the suction pump (i.e., dry suction).	A
33	Dental suction system pump	An electrically-powered dental suction pump used as the suction source of a dental suction system, dental treatment unit, etc.	B
34	Temporary mandibular condyle prosthesis	A sterile implantable device intended for the temporary reconstruction of the mandibular condyle of the temporomandibular joint (TMJ) typically in a patient undergoing ablative surgery requiring the removal of the mandibular condyle.	C
35	Temporomandibular joint disc	A sterile interpositional implant or interarticular disc, intended to permanently interface between the natural mandibular condyle and natural glenoid fossa (mandibular fossa) in the temporomandibular joint (TMJ).	C
36	Bar dental precision attachment	It connect removable partial dentures to fixed bridgework under a male/female locking mechanism.	A
37	Dental suction system disinfection control unit	An electrically-powered device intended to control the regular (typically daily) automated/semi-automated disinfection of a dental suction system tubing line.	B
38	Transgingival implant	A sterile device intended to be surgically implanted through the oral mucosa and gingiva to provide support and a means of retention for a dental prosthesis.	C
39	Zinc polycarboxylate dental cement	A non-sterile substance intended for professional use as a dental cement (e.g., luting agent, liner, base) and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between zinc oxide (ZnO) and aqueous solutions of polycarboxylic acid (e.g., polyacrylic acid).	B
40	Transmandibular implant	A sterile transosteal (transosseous) device [transmandibular implant (TMI)] intended to be surgically implanted through mandibular bone to provide support and a means of retention for a dental prosthesis, especially in a patient with an extremely atrophied/deformed mandible.	C

41	Pliable-polymer dental regeneration membrane, bio absorbable, ligated	A sterile bio absorbable material intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, by acting as a barrier to prevent the down-growth of soft tissue (connective tissue and epithelial cells) into the underlying bone during the healing period.	C
42	Pliable-polymer dental regeneration membrane, bio absorbable, tacked	A sterile bio absorbable material intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, by acting as a barrier to prevent the down-growth of soft tissue (connective tissue and epithelial cells) into the underlying bone during the healing period.	C
43	Dental surgical procedure kit, medicated, reusable	A collection of various dental instruments, dressings, pharmaceuticals and the necessary materials used to perform a dental surgical procedure.	C
44	Dental surgical procedure kit, medicated, single-use	A collection of various sterile dental instruments, dressings, pharmaceuticals and the necessary materials used to perform a dental surgical procedure.	C
45	Membrane fixation tack, bio absorbable	A sterile bio absorbable tack intended to be used to fix a pliable-polymer dental regeneration membrane in situ to aid in the regeneration of tooth support that has been lost due to periodontal disease or trauma.	C
46	Periodontal root surface regeneration material	A bio absorbable material intended to be used alone or in combination with bone graft materials for the regeneration of tooth support that has been lost due to periodontal disease or trauma. It is applied during periodontal flap surgery to the scaled and preconditioned root surface and forms an insoluble matrix that creates a suitable root surface for selective periodontal cell migration and cell attachment, which re-establishes the lost tooth support.	C
47	Periodontal tissue reconstructive material	A sterile viscous material intended to be injected into the buccal mucosa to treat deficiencies of the gingiva (e.g., interdental papillae), through augmentation, during the treatment of intermediate stage periodontal disease.	C
48	Bone matrix implant, human-derived	A sterile implantable device made primarily of human demineralized bone matrix (DBM) intended to fill bony voids or gaps caused by trauma or surgery, including use in the maxillofacial and/or mandibular bone.	C
49	Collagen dental regeneration membrane	A sterile, bio absorbable, animal-derived collagen (e.g., porcine) intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, and/or to regenerate bone or bone defects around dental implants and at sites intended for implant placement, by acting as a barrier to prevent the down-growth of soft tissue into the underlying bone during the healing period.	C
50	Dental cotton roll	It is intended as an absorbent, hard-packed cylinder (a roll) that is used as a saliva absorber from the oral cavity during dental procedures. It may also be used as a packing between the lip/cheek and the gum to give better examination/operative exposure.	A

51	Dental impression tray, single-use	The device is used mainly to facilitate the manufacturing of custom dental prostheses (e.g., dentures). This is a single-use device.	A
52	Preformed dental crown, permanent	A prefabricated prosthetic device designed to function as a permanent artificial covering to partially or fully replace the damaged crown of a tooth. It is available as a single prosthesis or multiple prostheses of various shapes and sizes, and may include one or more try-in prosthesis replicas and other devices intended to assist the restoration procedure.	B
53	Preformed dental crown, temporary	This device is commonly used during prosthodontic treatment or other restorative work required as a result of traumatic injury.	B
54	Zinc phosphate dental cement	A non-sterile substance intended for professional use as a dental cement and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between an oxide powder [the principal constituent of which is zinc oxide (ZnO)] and an aqueous solution of phosphoric acid.	B
55	Dental articulation paper forceps	A hand-held manual dental instrument designed for grasping and holding articulation paper during its application to a patient's oral cavity.	A
56	Dental dressing forceps, reusable	A hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity.	A
57	Dental dressing forceps, single-use	A sterile, hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity.	A
58	Rubber dam clamp forceps	A hand-held dental instrument used for the insertion and removal of rubber dam clamps.	A
59	Tooth extraction forceps	A hand-held manual dental surgical instrument shaped like pincers and designed for the extraction of teeth.	A
60	Dental amalgam mercury dispenser	A device with a valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form which is to be used to produce amalgam filling material.	A
61	Dental anaesthesia injection kit	A collection of sterile devices designed to inject dental anaesthetics into gingival tissue or the oral mucosa, while preventing or reducing the risk of accidental needle-stick injury, during restorative or surgical dental procedures.	B
62	Dental anaesthesia syringe cartridge	A plastic or glass container prefilled with a single dose of anaesthetic medication intended to be inserted into a dental anaesthesia syringe and injected into oral tissues for a dental procedure.	C
63	Dental anaesthesia syringe, intraligamentary	A hand-held manual dental instrument intended to be used to inject an anaesthetic agent under pressure via the periodontal ligament or into bone through an attached sterile needle. This is a reusable device.	C
64	Dental anaesthesia syringe, reusable	A hand-held manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle; a needle is not included.	B

65	Dental anaesthesia syringe, single-use	A sterile, hand-held, manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle (needle not included).	B
66	Dental anaesthesia syringe/needle	A hand-held manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an included sterile needle; the needle may be attached or detached.	B
67	Dental anaesthesia system	An assembly of devices used for the administration of a proportional mixture of oxygen (O2) and nitrous oxide (N2O) or medical air during dental surgical treatment.	C
68	Bite registration rim	A schematic model of the dental arch attached to a temporary or permanent base for recording jaw relationships.	B
69	Bite registration rim wax	A dental material (modelling wax) with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims). This is a single-use device.	A
70	Bite registration rim wax, plate	A dental material (modelling wax) delivered as prefabricated plates of wax with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims).	B
71	Calcium hydroxide dental cement	Use as a dental cement and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between calcium hydroxide and salicylic acid.	B
72	Ceramic artificial teeth	Prefabricated teeth made of ceramic (porcelain) for mounting on removable dentures or fixed partial dentures.	B
73	Dental soft-tissue matrix implant, animal-derived	A sterile, bio absorbable, animal-derived collagen (e.g., porcine) intended to be used to aid in the regeneration of oral soft tissue, lost due to periodontal disease or trauma, through promotion of new blood vessels and/or by providing a temporary scaffold for tissue ingrowth; it is indicated for various oral soft tissue augmentation procedures (e.g., alveolar ridge reconstruction, localized gingival augmentation, covering of recession defects and extraction sockets). It is a pliable material which may be fixed to soft tissues with sutures; it is applied to soft tissue during periodontal flap surgery and guided tissue regeneration (GTR) surgical procedures. This is a single-use device.	C
74	Dental Bonding Agents	A dental resin used in the bonding of light cured composites and acid modified composites to tooth structure.	B
75	Dental Etchant	The material is applied for temporary etching of dental hard tissue in order to condition the surface for bonding procedures.	B

76	Dental Prosthesis Priming Agent	A material primarily intended to be applied to a dental prosthesis (i.e., indirect restorative) immediately prior to insertion into a tooth structure to promote bonding to a prosthesis component during a dental procedure in the mouth.	B
77	Restorative Material	A dental luting agent, liner, base, pulp-capping material, pit/fissure sealant, and/or direct dental restorative material for restoration of cavities in teeth.	B
78	Orthodontic Adhesive	Used as a combined etchant and primer in orthodontic treatment used with/without light curing direct bonding orthodontic adhesive.	B
79	Dental Varnishes/ Glazing	A dental device intended to be applied to the surface of a restorative dental filling to attain a smooth, glaze-like finish on the surface.	B
80	Dental Cements	Intended for direct/indirect restoration (temporary/permanent) of tooth.	B
81	Dental Root Surface Conditioner	Assists in the debridement and cleaning of root canals (dental) Aids in the chemical breakdown of pulp soft tissue (dental).	B
82	Dental Cleansing Solution	A liquid used to clean cavities or root canals after preparation, and may also be used for disinfecting the cavity or root canal in endodontic procedures.	B
83	Endodontic Sealer	To fill and seal all pathways between the root canal and external surfaces of the tooth i.e., for permanent obturation of the root canal. Intended for use in procedure involving root filling, repair of root perforations, pulp capping and apexification.	B
84	Oral Cavity Abrasive Polishing Agent	An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth.	A
85	Root Canal Filling removal Solution	A liquid substance used in endodontic procedures for the softening and removal of root canal fillings. It will typically be introduced into the root canal using instruments. The device typically contains solvents and other elements (e.g., tetrachloroethylene, formamide, eucalyptol, excipients).	B
86	Dental Composite Resin Kit	A collection of non-sterile substances intended for professional use during dental restoration and prosthesis installation/repair which includes composite resin material and additional materials to support restoration (e.g., etching solution, bonding agent, primer, prosthesis bonding agents, unfilled resin sealant/coating agents), and may include dedicated disposable devices associated with application; it does not include non-resin based cement nor dental prosthesis.	B
87	Gingival Bleaching Protector	A non-sterile paste or gel-like substance designed to protect a patients gums from the hydrogen peroxide (H_2O_2) found in teeth whitening agents used during chairside light-curing bleaching of the teeth.	B
88	Dental Caries Removal Solution	A liquid substance used in dentistry to detect and remove caries from an infected tooth.	B

89	Denture Base Resin	A collection of resins and other devices and/or materials intended to be used in the dental laboratory to manufacture a complete or partial denture base (the portion of a denture that rests on the oral mucosa and retains the artificial teeth).	B
90	Polymer Based Prosthodontic Material	Light cured, methacrylate-based resin for creating reservoir space for bleaching trays is useful for laboratory procedures such as model, and die repair. It can be block out defects and under cuts on the stone models quickly and securely for precise abutment preparation.	B
91	Powered Surgical Drill Hand piece for Dental applications	A device that consists of a hand piece to which is connected a variety of attachments in order to achieve a number of cutting/inserting/trimming operations.	B
92	Orthodontic appliance, Band	Device for fixed orthodontic appliances. Device affixed to contour of tooth/teeth and cemented into place to support (pressure can be exerted on the teeth) orthodontic appliances or attachments.	B
93	Orthodontic Elastomeric	A tooth positioner/instrument intended to control settling/position and to minimize or eliminate relapse of the teeth after an orthodontic treatment.	A
94	Orthopaedic dental file	A hand-held dental surgical instrument used to enlarge the root canal, smooth out the root canal wall or shaping canals after they are previously cleaned by scratching/scraping with vertical reciprocating motion or rotary motion or plucking motion.	B
95	Dental endodontic enlarger	A device for enlarging and preparing the root canal, which probes, enlarges, and cleans the root canal by dental file, etc. The motion of the file includes vibrating, rotating, repeating rotation, reciprocating, and a combination of these motions.	B

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (153) – Part 1 **Date:** 11 OCT 2022

Subject: Classification of medical device pertaining to Oncology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, Appendix A. based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC (153) – Part 1
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA, Bhawan, New Delhi-110002

Notice

Classification of Medical Devices Pertaining to Oncology

S. No.	Medical Device Name	Intended Use	Risk class
1	FerriScan R2-MRI Analysis System	The FerriScan R2-MRI Analysis System is intended to measure liver iron concentration to aid in the identification and monitoring of non-transfusion dependent thalassemia patients receiving therapy with deferasirox.	C
2	Alternating electric field antimitotic cancer treatment system generator	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	C
3	Alternating electric field antimitotic cancer treatment system transducer array	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	C
4	Bladder instillation buffer solution	A sterile buffer solution intended to be used exclusively for bladder instillation to help create an optimal environment necessary for the effective treatment of superficial bladder cancer with a chemotherapy agent.	B
5	Breast 3-D infrared imaging/vascular analysis system	An assembly of mains electricity (AC-powered) devices intended for three-dimensional (3-D) breast imaging and breast vascular analysis, typically used with mammography screening to perform a breast cancer risk examination.	C
6	Colonic cytology sampling set	A collection of non-sterile devices intended to collect exfoliated colonic cells (colonocytes) from the surface of human rectal mucosa for colorectal cancer investigation and/or patient screening.	B
7	Cryosurgical set	A sterile collection of disposable devices used in conjunction with a cryosurgical unit as well as monitoring and other devices to perform a surgical technique that involves freezing a targeted area of tissue to damage and destroy cancer cells in the unwanted portions.	C
8	Capsular tension ring	A circular band intended to be used to enhance the mechanical stability of a subluxated crystalline lens capsule in the presence of weak or absent supporting zonules.	C
9	Electro cancer therapy system	An assembly of devices designed for the treatment of tumours and the destruction of their cancerous cells using low-voltage direct current of small intensity delivered via electrodes placed across the affected body area.	C

10	Electronic clinical breast examination system	A portable assembly of devices designed to electronically measure, map, document and store information about breast lesions/masses with regard to shape, size, location, consistency/relative hardness during a clinical breast examination (CBE)	B
11	Endocervical aspirator	A collection of devices designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction.	C
12	Alternating electric field antimitotic cancer treatment system	An assembly of portable devices designed to apply low-intensity, intermediate-frequency (100-300 kHz) alternating electric fields to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	D
13	Balloon kyphoplasty kit	A collection of sterile surgical instruments and devices used for the reduction of a vertebral compression fractures (VCFs) caused by trauma, cancer, or osteoporosis during a minimally invasive procedure commonly known as balloon kyphoplasty.	C
14	Accelerator system chair	A seat, typically with legs, that is a component of a therapeutic accelerator system, and used to support and position a seated patient during radiation therapy treatments involving the use of either a medical linear accelerator or non-linear accelerator.	C
15	Accelerator system quality assurance device	An instrument specifically designed to be used to check the calibration and performance of linear and non-linear medical accelerator systems used for radiation therapy applications, for quality assurance (QA) purposes	C
16	Acupressure wristband	A device designed to be worn on the wrist(s) for the application of pressure to the Nei-kuan (P6) acupressure point, the area identified to help relieve the sensation of nausea.	B
17	Anorectal brachytherapy system applicator, manual	A manual brachytherapy applicator specifically designed to be used in radiation therapy treatments of the rectum and/or anus.	C
18	Anorectal brachytherapy system applicator, remote-afterloading	A remote afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the rectum and/or anus.	C
19	Antimicrobial postsurgical brassiere	A woman's undergarment which includes antimicrobial properties designed to support and/or contour the breast(s) or hold a dressing in place after surgical intervention (e.g. thoracic surgery, mastectomy, lumpectomy)	A
20	Antimicrobial postsurgical female underpants	It is intended for use during medical treatment (e.g., chemotherapy) or be used to protect the skin following treatment with a medication (e.g. ointment, cream). It is specifically designed for patient support/comfort in the home or healthcare facility. This is a reusable device.	A
21	Blood photochemical treatment agent	A sterile photochemical agent (psoralen) intended to be used in conjunction with ultraviolet A (UVA) irradiation to eliminate nucleated cells from blood or blood components (e.g. plasma, leukocyte-enriched blood fraction).	C
22	Brachytherapy radionuclide phantom, test object	A non-tissue configured model designed to mimic the functional/physical characteristics of normal or diseased human organs during performance evaluations of brachytherapy system	A

		components or radiation therapy treatment planning devices.	
23	Brachytherapy source spacer	A sterile, bioabsorbable device designed to separate radioactive sources of the seed type that are permanently implanted in close proximity to a selected localized tumour, to increase the distribution of radioactivity to the tumour.	C
24	Brachytherapy system remote-afterloading operator console	A mains electricity (AC-powered) component of a remote-afterloading brachytherapy system intended to function as the primary control panel for the remote afterloader. It typically includes hardware and software that allows for information display and/or transfer, data processing, analysis, and information archiving functions; it may also be intended to interface with other devices (e.g., radiation therapy treatment planning computer) as part of a picture archiving and communication system (PACS).	C
25	Breast binder	A strip or roll of fabric or plastic material applied to the breast or breasts for soft tissue support. This is a single-use device.	A
26	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the breast. It is typically designed for temporary implantation within the breast and serves as a guide for computer-controlled placement and removal of single or multiple radioactive sources. Included are various types of applicators such as hollow needles, tubes, or catheters, and their associated components. This is a single-use device.	C
27	Breast transilluminator	A mains electricity (AC-powered) transilluminating device with a built-in light source using low intensity emissions of visible light and near-infrared radiation (700 to 1050 nm) that is transmitted through the female breast to visualize translucent tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities. This device may also be known as a diaphanoscope.	A
28-a	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for intracorporeal (endosonography or endoscopic) ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast.	C
28-b	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for extracorporeal ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast	B
29	Cervical cone knife	A surgical, manually-operated, instrument that is inserted into the vagina and designed for excising a sample of abnormal tissue, e.g., indicated by the presence of precancerous changes, from the cervix.	C
30	Cervical cytology scraper, reusable	blunt surgical instrument used to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a reusable device.	A
31	Cervical cytology scraper, single-use	A hand-held, manual, blunt surgical instrument designed to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a single-use device.	B

32	Coronary artery brachytherapy system applicator, manual-afterloading	A sterile flexible tube intended to deliver/remove radiation therapy sources into a coronary artery, typically into the lumen of an implanted stent, as part of a manual-afterloading brachytherapy system. It is introduced into the patient and subsequently connected to the brachytherapy system source transfer device; it includes radiopaque markers to monitor the position of the radiation source. Disposable devices associated with the procedure may be included (e.g., syringe, connectors). This is a single-use device.	D
33	Cytotoxic waste receptacle	A device designed as a container to allow the safe deposit, collection and storage of cytotoxic materials (e.g., chemotherapy/antineoplastic drugs).	A
34	Electroporation therapy system	A mobile assembly of devices designed to apply electrical impulses to the tissue to enable electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)] and genetic materials [electrogenetherapy (EGT)], to reach the cytoplasm.	C
35	Electroporation therapy system endoscopic applicator	A sterile, patient-contact component of an electroporation therapy system intended to fit onto the distal tip of an endoscope and connect to an electroporation therapy system generator to deliver electrical impulses to tissues during endoscopy as part of electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)], to reach the cytoplasm.	C
36	Externally-propelled flexible video colonoscope	A non-sterile endoscope with a highly flexible sleeve and distal tip intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract].It is used for the screening of colorectal cancer and the detection of other diseases of the lower GI tract. This is a single-use device.	B
37	Extravascular-circulation hyperthermia system	An assembly of devices designed to produce and control heated fluids circulated within a vessel applied to the body (e.g., vest, mattress, jacket, band, pad, body wrap, catheter, probe) for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions.	B
38	Extravascular-circulation hyperthermia system applicator, extracorporeal	A vessel applied to the outside of the body (e.g., in the form of a jacket, vest, body wrap, cushion, blanket, or mattress) that incorporates tubing through which heated fluids are circulated for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions. he applicator typically includes a thermometry component that monitors the temperature of the applicator during operation. The applicator includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a reusable device.	A
39	Extravascular-circulation hyperthermia system applicator, intracorporeal	A component of a hyperthermia system that typically consists of catheter-enclosed tubing which is introduced into the body either manually or endoscopically. Heated fluid is circulated through the applicator's tubing for localized heating to treat malignant tumours, benign growths, or other disease-related conditions. The applicator	C

		(also called an interstitial applicator or probe) typically includes a thermometry component that monitors the temperature of the applicator during operation; it also includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a single-use device.	
40	Facial prosthesis	An externally-applied device intended to be used as an artificial substitute for parts or sections of the face [e.g., nose, eye(s), eye brows, upper lip] to help restore facial appearance.	B
41	Fixed-aperture therapeutic x-ray system collimator	A non-automated, x-ray beam-limiting device that is a component of a therapeutic x-ray system and whose opening size/length/shutter assembly is fixed. It is used in radiation therapy applications to limit the effects of scattered radiation and to protect the patient by limiting or eliminating exposure to non-target body areas during treatment. This device is specifically designed for use with an x-ray simulation or therapeutic x-ray system.	C
42	Flexible fibre optic bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B
43	Flexible fibre optic mediastinoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the mediastinum (the intrapleural space located behind the sternum). It is inserted into the body through an artificial orifice created by an incision made during mediastinoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to examine structures such as lymph nodes during a staging evaluation of lung cancer, or to establish the diagnosis of a tumour that is localized to the mediastinum. This is a reusable device.	C
44	General-purpose infusion pump, mechanical, single-use	A portable, non-electric, mechanically-powered device designed to be operated by healthcare professionals for dispensing a single dose of fluid medication (e.g., for antibiotic therapy, chemotherapy, analgesia). It consists of an empty reservoir intended to be filled with medication, a flow-rate regulator and a non-sterile (sterilizable) administration line intended to be connected to an infusion catheter (not included) for intravenous (IV), subcutaneous, intramuscular, or epidural administration. It may include flow and fluid level mechanical indicators and may be worn by the patient in and outside of healthcare settings. This is a single-use device.	C
45	Flexible ultrasound bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device typically through a fibre optic bundle or a video system, and an ultrasound probe. The probe may be built-in or inserted through a dedicated lumen so that its	B

		distal tip is positioned adjacent to that of the endoscope. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	
46	General-purpose infusion pump, mechanical, reusable	A non-electric, mechanically-powered (e.g., a spring mechanism) device designed for the continuous or intermittent infusion of medication, typically for antibiotic therapy, chemotherapy, or pain management by intravenous (IV), subcutaneous, intramuscular, or epidural routes. It is primarily designed to be worn by the patient during ambulation in the home. It may be used for patient-controlled analgesia (PCA), and may include mechanical indicators for flow and fluid level status. This is a reusable device.	C
47	Flexible video bronchoscope, reusable	An endoscope with a flexible inserted portion for endoscopic procedures of the airways and tracheobronchial tree (i.e., bronchoscopy). It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by a video system with a charge-coupled device (CCD) chip at the distal end and the images showing on a monitor. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B
48	Robotic Guidance system for image Guided procedures	The Medical Device is an accessory to an imaging system (CT, CT-PET) intended for the spatial positioning and orientation of an instrument guide. A surgeon then manually advances one or more instruments for percutaneous image guided interventional procedures through the instrument guide. The device is not intended to make any contact with the patient.	B

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. IVD/Misc/196/2020 Date: 25 OCT 2023

Subject: Classification of *In-vitro* Diagnostic Medical Devices under the provisions of Medical Devices Rules, 2017 - Regarding.

Safety, quality and performance of Medical Devices and In-vitro Diagnostic Medical Devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules, made there under. For the regulation of Medical Devices and In-vitro Diagnostic Medical Devices with respect to the import, manufacture, clinical investigation, clinical performance evaluation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78(E) dated 31.01.2017 which is already implemented from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the in-vitro Diagnostic Medical Devices based on the intended use, risk associated with the device and other parameters specified in the First Schedule.

Updated list of In-vitro Diagnostics Medical Devices placed at Annexure A (*Updated*), Annexure B (*Updated*), Annexure C, Annexure D (*added*), Annexure E (*added*) is subjected to the followings:

1. General intended use given against each of the device is for guidance to the applicants who intends to furnish application of import or manufacture of medical Devices under the provisions of Medical Devices Rules, 2017. However, as device may have specified intended use as specified by its manufacturer.

2. This list is dynamic and is subjected to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General of India

To,

CDSCO Website

Annexure A (*Updated*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD Analyzers) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Clinical chemistry	Alcohol body-fluid analyser	A	An analyzer (other than near-patient testing) intended to determine the concentration of alcohol in a body-fluid specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing to determine the concentration of alcohol in a body-fluid specimen. It is intended for in-vitro diagnostic use.
2		Amino acid analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of individual amino acids in a protein sample obtained from a clinical specimen. It is intended for in-vitro diagnostic use.
3		Bilirubinometry analyser	A	A device (other than near-patient testing) that measures directly or indirectly the bilirubin concentration in blood or other samples. It is intended for in-vitro diagnostic use.
			C	A device intended to be used for near-patient testing that measure directly or indirectly the bilirubin concentration in blood or other samples. It is intended for in-vitro diagnostic use.
4		Catecholamines analyser	A	A device that measures catecholamine concentration in biological samples. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Clinical chemistry	Chemiluminescent immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.
6		Chloride coulometric titration analyser	A	An analyzer intended to be used for the quantitative measurement of chloride in a clinical specimen using a coulometric titration. It is intended for in-vitro diagnostic use.
7		Cholesterol analyser	A	A device that measures the cholesterol in serum/whole blood. It is intended for in-vitro diagnostic use.
8		Clinical chemistry analyser	A	An analyzer intended to be used for the qualitative and/or quantitative determination of one or multiple clinical chemistry analytes in a clinical specimen. It is intended for in-vitro diagnostic use.
9		Creatinine analyser	A	A device that measures creatinine concentration in urine or serum sample. It is intended for in-vitro diagnostic use.
10		Enzyme analyser	A	A device that measures the enzymatic activity of the sample for diagnosis. It is intended for in-vitro diagnostic use.
11		Glycated haemoglobin (HbA1C) analyser	A	An analyzer intended to be used for the quantitative measurement of glycated haemoglobin (HbA1c) in a clinical specimen. It is intended for in-vitro diagnostic use.
12		High performance liquid chromatography analyser	A	An analyzer designed to use high performance liquid chromatography (HPLC) for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.
13		Identification and Antibiotic susceptibility analyser	A	A device that identifies infectious/ pathogenic microorganisms by photometry such as absorption, fluorescence and luminescence, and measures the susceptibility to therapeutic drugs. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
14	Clinical chemistry	Ion-selective analyser	A	An analyzer intended to be used for the quantitative measurement of electrolytes and/or other ions in a clinical specimen. It is intended for in-vitro diagnostic use.
15		Lactate analyser	A	An analyzer used to determine the concentration of lactate in various body fluids using the lactate oxidase fixation electrode. It is intended for in-vitro diagnostic use.
16		Lipid profile analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of lipid profile analytes in a clinical specimen. It is intended for in-vitro diagnostic use.
17		Nitrogen body-fluid-sample analyser	A	An analyzer used to analyse the nitrogen (N2) content in a body fluid. It is intended for in-vitro diagnostic use.
18		Protein analyser	A	A device used to measure concentration and to identify specific proteins present in a clinical specimen. It is intended for in-vitro diagnostic use.
19		Radioimmunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen using an immunological method which utilizes a radiometric detection system to detect the presence of immune complexes labelled using a radioisotope. It is intended for in-vitro diagnostic use.
20		Urine analyser	A	An analyzer (other than near-patient testing) intended to be used for the qualitative and/or quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing for the qualitative and/or quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen. It is intended for in-vitro diagnostic use.
21	Clinical chemistry	Biochemistry Analyzer	A	An analyzer intended for measuring and analyzing various biologic and chemical elements of human body fluid. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
22		Breath-alcohol test system	A	A device intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
23		Nitric oxide breath analyzer	B	A device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to establish clinical and laboratory assessments of asthma. It is intended for in-vitro diagnostic use.
24		Osmolality test system	A	A device intended to measure ionic and non-ionic solute concentration in body fluids, such as serum and urine. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances. It is intended for in-vitro diagnostic use.
25		Osmometer	A	A device intended to measure the osmotic pressure of body fluids. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders. It is intended for in-vitro diagnostic use.
26		Plasma oncometer	A	A device intended to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the variations are useful in the diagnosis and treatment of these disorders. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
27		Refractometer	A	A device intended to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such a plasma total proteins and urinary total solids. Measurements obtained by this device are used in the in-vitro diagnosis and treatment of certain conditions.
28		Urea Breath Analyzer	A	An analyzer intended for the use in the detection of urease (using breath sample) associated with H. pylori in the human stomach and is indicated as an aid in the initial diagnosis of H. pylori infection. It is intended for in-vitro diagnostic use.
29		Viscosimetric analyser	A	A device that measures the resistance of fluid against the flow by intermolecular force. It is also used for the analysis of whole blood, serum or plasma. It is intended for in-vitro diagnostic use.
30	Other Clinical chemistry analyser	Other Clinical chemistry analyser (other than near patient testing)	A	
31		Other Clinical chemistry analyser (intended to be used near patient testing)	C	
32	Hematology	ABO/Rh(D) blood grouping analyser	A	A lab based analyzer (other than near-patient testing) intended to be used to perform blood group testing to determine the ABO and Rh(D) status of clinical specimens. It is intended for in-vitro diagnostic use.
			D	An analyzer (for near-patient testing) intended to be used to perform blood group testing to determine the ABO and Rh(D) status of clinical specimens. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
33		Blood cell count analyser	A	A device that quantifies the formed elements in the blood (i.e., erythrocytes, leukocytes, and platelets) by electro impedance, optical scattering or dye binding. It is intended for in-vitro diagnostic use.
34		Blood coagulation analyser	A	An analyzer (other than near-patient testing) intended to be used for the qualitative and/or quantitative in vitro determination of one or multiple coagulation components involved in haemostasis in a clinical specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing for the qualitative and/or quantitative in vitro determination of one or multiple coagulation components involved in haemostasis in a clinical specimen. It is intended for in-vitro diagnostic use.
35		Blood group/antibody screening analyser	A	An analyzer intended to be used to perform pre-transfusion blood group testing, red cell antibody screening/identification and/or red cell phenotyping of clinical specimens or donor specimens in order to determine suitability for transfusion or transplantation. It is intended for in-vitro diagnostic use.
36		Co-oximetry analyser	B	An analyzer intended to be used for the quantitative in vitro measurement of oxygen saturation, haemoglobin derivatives and other calculated haemoximetry parameters in a whole blood specimen. It is intended for in-vitro diagnostic use.
37		Erthrocyte sedimentation rate (ESR) analyser	A	An analyzer intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. It is intended for in-vitro diagnostic use.
38		Flow cytometry analyser	A	An analyzer intended to be used to count, examine and/or sort cells or microscopic particles in a clinical specimen. It is intended for in-vitro diagnostic use.
39		Heparin analyser	A	A device that measures heparin concentration in blood samples. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
40		Osmotic fragility analyser	A	An analyzer intended to be used for the determination of the osmotic fragility of red blood cells in a whole blood specimen. It is intended for in-vitro diagnostic use.
41		Reticulocyte analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of reticulocytes, or immature red blood cells in a clinical specimen. It is intended for in-vitro diagnostic use.
42		Blood gas analyser	A	An analyzer (other than near-patient testing) intended to be used for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and/or partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters in a clinical specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and/or partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters in a clinical specimen. It is intended for in-vitro diagnostic use.
43		Haemoglobin analyser	A	An analyzer intended to be used to determine the concentration of haemoglobin in a clinical specimen. It is intended for in-vitro diagnostic use.
44		Hematology Analyzer	A	An analyzer intended to analyze in-vitro samples of whole blood to provide complete blood count, leucocyte differential count, classify and/or enumerate various parameters using the impedance and spectrophotometry techniques. It is intended for in-vitro diagnostic use.
45		Thromboelastrogram (TEG) Hemostasis Analyzer	A	An analyzer intended to provide a quantitative and/or qualitative indication of the hemostasis state of a blood sample by monitoring, measuring, analyzing and reporting hemostasis parameter information, in order to assist in the assessment of patient clinical hemostasis conditions. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
46		Platelet aggregation analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro examination of platelet function in a clinical specimen, by inducing platelet aggregation through the addition of platelet aggregating agents. It is intended for in-vitro diagnostic use.
47	Other hematology analyser	Other hematology analyser (other than near patient testing)	A	
48		Other hematology analyser (intended to be used near patient testing)	C	
49	Immunology	Densitometry analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of the staining pattern intensity on film, acetate or other composite medium to separate and/or visualize the individual components of a clinical specimen. It is intended for in-vitro diagnostic use.
50		Enzyme immunoassay (EIA) analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers, in a clinical specimen, using an immunological method. It is intended for in-vitro diagnostic use.
51		Fluorescent immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
52		Immunology analyzer	A	An analyzer used to identify and detect the concentration of specific substances in a sample, using immunoassay methodologies. It is intended for in-vitro diagnostic use.
53		Immunofluorescent analyser	A	A device used to measures the volume of antigen/antibody present in the components of body fluids. It is intended for in-vitro diagnostic use.
54		Microarray analyser	A	An analyzer intended to be used for the in vitro determination of multiple target analytes in a single clinical specimen using oligonucleotide capture molecules arranged in a consistent pattern on a slide, chip or membrane. It is intended for in-vitro diagnostic use.
55	Immunology	Particle-counting immunoassay analyser	A	A device for immunological measurement by counting latex aggregates based on the light scattering. It is intended for in-vitro diagnostic use.
56		Photometric immunoassay analyser	A	An analyzer, intended to be used to scan an immunoassay reagent vehicle after exposure to a clinical specimen, to provide a quantitative, semi-quantitative and/or qualitative in vitro determination of chemical substances and/or biological markers in a clinical specimen, using photometry. It is intended for in-vitro diagnostic use.
57	Microbiology	Antimicrobial susceptibility analyser	A	An analyzer intended to be used for the in vitro determination of an antimicrobial susceptibility profile by monitoring the growth rate of a microbiological organism from a clinical specimen and/or culture isolate when exposed to a range of antimicrobials. It is intended for in-vitro diagnostic use.
58		Blood culture analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of microorganism growth in a blood culture preparation or other clinical specimen, with or without subsequent identification of the organism. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
59		Gene analyser	A	A device that analyzes the sequence information of nucleic acid molecules extracted from biological samples. It is intended for in-vitro diagnostic use.
60		Immunoturbidimetric analyser	A	A light scattering analyzer that quantifies the analytes in the body fluid by measuring the light scattering intensity from the immune complex generated in the reaction between analyte and antibody. It is intended for in-vitro diagnostic use.
61	Microbiology	Microorganism identification analyser	A	An analyzer intended to be used for the identification of bacteria and/or yeast isolated from clinical specimens by characterizing their morphology, substrate utilization and/or biochemical reactivity, using growth detection technology. It is intended for in-vitro diagnostic use.
62		Nucleic acid amplification (PCR) analyser	A	An analyzer intended to amplify target deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) in a clinical specimen. It is intended for in-vitro diagnostic use.
63		Yeast/fungi identification analyser	A	An analyzer intended to be used for the identification of yeast and/or fungi isolated from clinical specimens by characterizing their morphology, substrate utilization and/or biochemical reactivity, using growth detection technology. . It is intended for in-vitro diagnostic use.
64	Clinical chemistry / Microbiology / Toxicology	Gas chromatography analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.
65	Clinical chemistry / Microbiology/ Hematology	Mass spectrometry analyser	A	An analyzer intended to be used for the qualitative and/or quantitative determination of the chemical composition of a clinical specimen by ionizing the specimen and separating the resulting ions according to mass using an electrical and magnetic field. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
66	Clinical chemistry / Immunology	Nephelometry immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen using an immunological method which utilizes a nephelometric detection system. It is intended for in-vitro diagnostic use.
67	Gastroenterology and Urology	Faecal occult blood immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of faecal occult blood, using an immunological method to detect or measure haemoglobin in a clinical stool (faeces) specimen. It is intended for in-vitro diagnostic use.
68	Obstetrical and Gynecological	Spermatozoa/semen analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro examination of a semen specimen to assess volume, spermatozoa concentration, motility and/or morphological characteristics. It is intended for in-vitro diagnostic use.
69	Immunology	Automated indirect immunofluorescence microscope	A	A device that acquires, analyzes (results), stores, and displays digital images of indirect immunofluorescent slides. It is intended to be used as an aid in the determination of antibody status in clinical samples. It is intended for in-vitro diagnostic use.
70	Immunology	ELISA Plate Reader	A	An analyzer intended for in vitro diagnostic use to measure radiant energy emitted, transmitted, absorbed, or reflected under controlled conditions and interpret ELISA test results. It is intended for in-vitro diagnostic use.
71	Microbiology	Microscope	A	A device intended to enlarge images of specimens, preparations and/or cultures (to gain its physiological or morphological information) for in-vitro diagnostic use.
72	Toxicology	Lead test analyser	A	A device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning. . It is intended for in-vitro diagnostic use.

Annexure B (*Updated*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD Instruments) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Blood smear cassette	A	A device designed to be inserted into an automated microscope slide processing instrument to create a blood smear on a microscope examination slide for subsequent staining and/or microscopic analysis. It is intended to be used for an in vitro diagnostic procedure.
2	Blood smear instrument	A	A manual laboratory instrument intended to be used to create a blood smear on a microscope examination slide for subsequent staining and/or microscopic analysis. It is intended to be used for an in vitro diagnostic procedure.
3	Blood tube mixer	A	An instrument intended to be used for the mixing of blood or other biological fluids contained in blood tubes or other similar specimen receptacles using continuous motion or agitation. It is intended to be used for an in vitro diagnostic procedure.
4	Blood component separator	A	A device designed for the separation of whole blood or previously centrifuged blood into components for further processing or storage. It is typically used for an in vitro diagnostic procedure, and is not donor or patient connected.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Cell washer	A	An instrument intended to be used to separate red blood cells from whole blood and wash the intact red blood cells, to remove plasma, debris and/or any other extraneous material so they are free from interfering substances. It is intended to be used for an in vitro diagnostic procedure.
6	Colony counter	A	A device designed to count bacterial coloniesin a culture. It is intended to be used for an in vitro diagnostic procedure.
7	Inoculating loop	A	A device intended to be used to transfer and spread inoculum from a clinical specimen and/or culture isolate into a culture medium for subsequent in vitro diagnostic processing and/or testing.
8	Magnetic particle separation instrument	A	An instrument intended to be used for the automated pre-analytical extraction of specific molecules from a clinical specimen using magnetic particle separation techniques. It is intended to be used for an in vitro diagnostic procedure.
9	Microbial incubator/imaging system	A	A device intended to provide ideal conditions for microbial growth with an incubator, and to capture digital images of the specimens contained within the incubator at specified time intervals. It is intended to be used for an in vitro diagnostic procedure.
10	Microplate seal roller	A	A manually-operated device intended to firmly apply a seal to a microplate. It is intended to be used for an in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
11	Microplate washer	A	An instrument intended to be used for washing microplates. It is intended to be used for an in vitro diagnostic procedure.
12	Microscope slide coverslipper	A	An instrument intended to be used to apply a coverslip over a microscope examination slide to protect the fixed/stained specimen from mechanical forces or environmental exposure prior to microscopic examination and/or long-term storage of the slide. It is intended to be used for an in vitro diagnostic procedure.
13	Microscope slide hybridization/ denaturation incubator	A	An instrument intended to be used for the incubation of microscope slides for the denaturation and/or hybridization of a clinical specimen as part of an in situ hybridization (ISH) and/or fluorescence in situ hybridisation (FISH) protocol. It is intended to be used for an in vitro diagnostic procedure.
14	Microscope slide maker/stainer	A	An instrument intended to be used to prepare, transfer or fix blood, tissue or other clinical specimens onto microscope examination slides, and then stain the slides using one or more biological or cytochemical staining solutions in preparation for subsequent microscopic analysis. It is intended to be used for an in vitro diagnostic procedure.
15	Microscope slide washer	A	An instrument intended to be used for washing microscope slides by applying a flow of washing solution as part of the processing steps required to perform an in vitro diagnostic assay. It is intended to be used for an in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
16	Nucleic acid sample preparation instrument	A	An instrument intended to be used for the pre-analytical preparation of samples for downstream nucleic acid analysis. It is intended to be used for an in vitro diagnostic procedure.
17	Slide-mounted-tissue dissection system	A	An assembly of devices designed to be used for dissection of microscope-slide-mounted tissue specimens under digital image guidance, allowing the user to digitally preselect the target dissection area with high precision. Excised tissues are suctioned into a sample tube for subsequent histopathology analysis. It is intended to be used for an in vitro diagnostic procedure.
18	Specimen processing instrument	A	An instrument or platform intended to be used for the automated pre-analytical preparation of a clinical specimen (excluding specimens for microbial culture), which may include the sampling, diluting, and/or aliquoting of clinical specimens and/or any post-analytical processing required, including labelling, storage and/or location data. It is intended to be used for an in vitro diagnostic procedure.
19	Cell-freezing apparatus	A	A device used to freeze human red blood cells. It is intended to be used for an in vitro diagnostic procedure.
20	Centrifuge	A	An instrument intended to separate, sediment, spin down aqueous solutions and solvent suspensions of differing densities in compatible sample containers. It is intended to be used for an in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
21	Cold plate	A	A device intended for chilling and blocking out of histological tissue samples in paraffin blocks. It is intended to be used for an in vitro diagnostic procedure.
22	Electrophoresis apparatus	A	An instrument intended to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobulins on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders. It is intended to be used for an in vitro diagnostic procedure.
23	Hot plate	A	A device designed with heating plate with high heat output and precise temperature control, suitable for flattening and drying cut histological tissue specimens in molten paraffin. It is intended to be used for an in vitro diagnostic procedure.
24	Microscope glass slide	A	A device intended for mounting Formalin Fixed Paraffin Embedded (FFPE) tissue sections/ specimens, suitable for cellular and tissue specimen preparation for microscopic analysis intended to be used for an in vitro diagnostic procedure.
25	Paraffin Dispenser	A	Paraffin or Wax dispenser is an instrument that melts the solid paraffin, maintains it in its molten form and dispenses it as and when required. The dispenser is separately heated to maintain the same temperature as the paraffin reservoir. It is used in Histopathology, Forensic Medicine and Anatomy Lab, where wax embedded moulds or blocks are prepared for in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
26	Paraffin flotation bath	A	A device designed for use as a heated, distilled water floating out bath for the manipulation and location of paraffin wax sections onto glass slides, it is used for in vitro diagnostic procedure.
27	Pipette/ Micropipette	A	An instrument designed and constructed for accurate and precise liquid handling, specifically intended by the manufacturer to be used for in vitro diagnostic examinations/procedures. It is intended to dispense liquid (sample/specimen/buffer solutions) in appropriate volume range in combination with matching pipette tips.
28	Tissue embedding system	A	An instrument meant for embedding histological tissue specimens in molten paraffin for use in pathology laboratories. It is intended to be used for an in vitro diagnostic procedure.
29	Any other instrument intended for diagnostic purpose	A	

Annexure C

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD Software) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Software)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Cancer cell marker/morphology image-analysis software	C	A software program with specific image analysis algorithms intended to be used in a digital pathology laboratory to assist in the analysis of immunohistochemically- or histologically-stained clinical specimens for the quantitative detection of cell markers or changes in tissue architecture and/or cell morphological/physiological characteristics associated with any type of cancer, performed during in vitro diagnostic (IVD) testing.
2	Cancer risk assessment interpretive software	C	An interpretive software program intended to be used in the assessment of risk for developing cancer, by using IVD results of the qualitative and/or quantitative detection of one or multiple cancer-specific biomarkers in a clinical specimen.
3	Cardiovascular risk/probability assessment interpretive software	C	An interpretive software program intended to be used in the assessment of risk/probability for having a cardiovascular condition or event, by using results of the qualitative/quantitative clinical specimen in vitro diagnostic (IVD) tests.
4	Congenital defect/syndrome risk assessment interpretive software	C	An interpretive software program intended to be used in the assessment of risk for the presence of a congenital medical defect and/or condition of a foetus. in vitro diagnostic (IVD) results of various maternal/foetal biochemical, hormonal and/or ultrasound markers.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Software)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Human genomic analysis interpretive software	C	An interpretive software program intended to be used for the analysis and visualization of human genome data from in vitro diagnostic (IVD) results obtained through molecular genetic testing. It provides predictive and/or diagnostic information used in the assessment of adverse health condition risk, disease prevention, and/or health management.
6	Laboratory instrument/analyser application software	A	A software program intended to be used with an in vitro diagnostic instrument/analyser or a data management device connected to the IVD instrument/analyser, to facilitate user-controlled device function.
7	Microbial identification interpretive software	A	An application software program intended to be used to identify microbial species (bacterial, fungal) using results from microbial cultures and laboratory biochemical tests. Results from an in vitro diagnostic medical device (IVD) are input and the name(s), and reliability of possible microbial species returned. It is intended for use in a microbiology laboratory.
8	Osteoporosis risk assessment interpretive software	A	An interpretive software program intended to be used in the assessment of risk for developing osteoporosis. This interpretive software program typically combines patient demographics and the in vitro diagnostic (IVD) results of the qualitative and/or quantitative detection of one or multiple proteins in a tissue sample to establish an individual risk score that may be used to guide patient management.

Note:

- Software, which drives a device or influences the use of a device, falls automatically in the same class.
- Software that is not incorporated in an *in vitro* diagnostic medical device shall be classified using the classification provisions as specified in paragraph 2 of Part II of First Schedule of Medical Devices Rules, 2017.

Annexure D (*Added*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD- Specimen receptacle) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Blood Collection Tube	A	A device, whether vacuum type or not, with/without coating (coating such as EDTA, heparin, silicones, blood clot activators, inhibitors, etc.), specifically intended by its manufacturer for the primary containment of predetermined volume of blood derived from human or animal body, for the purpose of *in vitro* diagnostic examinations.
2	Sample containers	A	A device specifically intended by its manufacturer for the primary containment of specimens derived from human or animal body, for the purpose of *in vitro* diagnostic examinations.
3	Arterial Blood Gas (ABG) Sampler	A	A device (sampler/syringe) for Blood Gas Analysis (without needle) which is preheparinized, electrolyte-balanced intended for the collection of arterial blood samples and to connect with a Blood Gas Analyzer for pH, blood gas, oximetry, electrolyte and metabolite analysis. It is intended for the purpose of *in vitro* diagnostic examinations.
4	Microcuvette	A	A device intended for sample collection and to measure appropriate volume of blood (Capillary, venous and arterial whole blood) directly from the skin surface by capillary action. It is intended for the purpose of *in vitro* diagnostic examinations.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Other Specimen Receptacles (vacuum type or not) without needle used for the collection of Blood, Urine, Stool, Sputum, Semen, etc., for purpose of specimens collection intended for in-vitro diagnostics purpose.	A	

Annexure E(*Added*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices	Risk class as per Part –II First Schedule of MDR 2017	Intended use
1.	COVID-19 IVD	Rapid/ELISA/CLIA (Serology based)	C	Used for In-Vitro diagnosis of covid-19
		RT-PCR/LAMP (Molecular Based)	C	Used for In-Vitro diagnosis of covid-19
		Antigen Test	C	Used for In-Vitro diagnosis of covid-19
		Antigen Home test	C	Used for In-Vitro diagnosis of covid-19
2.	RNA extraction kits	Ribonucleic acid (RNA) Extraction Kits	C	Ribonucleic acid (RNA) Extraction Kits intended for specimen derived from human or animal body for In-Vitro diagnostics purpose.
3.	DNA extraction kits	Deoxyribonucleic acid (DNA) Extraction Kits	C	Deoxyribonucleic acid (DNA) Extraction Kits intended for

				specimen derived from human or animal body for In-Vitro diagnostics purpose.
4.	Viral Transport Medium (VTM)	Viral Transport Medium (VTM)	A	Viral Transport Medium (VTM) for specimen derived from Human or animal body intended for In-Vitro Diagnosis.
5	Reagents/kits for detection markers for congenital disorders	Sickle Cell IVD	C	Used for In-Vitro diagnosis of Sickle Cell

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COMPANY PROFILE

Established in 2007, Pharmadocx provides consultation services to get License for Manufacturing of Medical Devices on Form MD-5, MD-9 & Import License on MD-15. We have so far setup more than 100 Medical Devices Plants & got them MD license.

Plant Setup Services- We design premises as per clients product capacity needs. We provide Civil Architectural plans, Clean Room Plan of ISO Class 7, HVAC Plan, Plumbing Plan, Electrical Plan, Equipment Plan. We design the facility as per MDR Rules 2017, US-FDA21CFR Part 820, CE Guidelines. We design the facilities for efficient working with requisite cleanliness levels.

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