(घ) प्ररूप एमडी-5 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ;

(ङ) प्ररूप एमडी-6 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

[फा. सं. एक्स.11014/10/2022-डीआर]

डॉ. मनदीप के भण्डारी, संयुक्त सचिव

टिप्पण : चिकित्सा युक्ति नियम, 2017, राजपत्र में अधिसूचना सं. सा.का.नि. 78(अ), तारीख 31 जनवरी, 2017 द्वारा प्रकाशित किए गए थे और अधिसूचना सं. सा.का.नि. 754(अ), तारीख 30 सितंबर, 2022 द्वारा अंतिम बार संशोधित किए गए थे ।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 14th October, 2022

G.S.R. 777(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017 was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 710(E), dated the 20th September, 2022 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of seven days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on 20th September, 2022;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), and subject to *ex post* consultation with the Drugs Technical Advisory Board and consideration of suggestions of the Board in accordance with the provisions of the said sections, the Central Government hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (1) These rules may be called the Medical Devices (Sixth Amendment) Rules, 2022.

   (2) These rules shall come into force on the date of their publication in the Official Gazette.

2. In the Medical Devices Rules, 2017 (hereinafter referred to as the said rules), in rule 13,—

   (a) in sub-rule (2), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

   (b) in sub-rule (3), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

3. In the said rules, in rule 14, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

4. In the said rules, after rule 19F, the following shall be inserted, namely:—

"CHAPTER IIIB

REGISTRATION OF CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICES

19G. Application of this Chapter.— (1) This Chapter shall be applicable to all non-sterile and non-measuring devices classified as Class A medical devices as per the First Schedule (herein in this chapter referred to as Class A non-sterile and non-measuring medical device).

(2) The medical devices referred to in sub-rule (1) shall be registered through an identified online portal established for the purpose.

19H. Uploading of information for registration.— (1) The manufacturer of a Class A non-sterile and non-measuring medical device shall upload the information specified in sub-rule (2) relating to that medical device for registration on the Online System for Medical Devices.

(2) The manufacturer shall upload the following in the Online System for Medical Devices, namely:—

(i) name and address of the manufacturing site;

(ii) details of Class A non-sterile and non-measuring medical devices to be provided:

Generic name	Brand Name (if registered under the Trade Marks Act, 1999)	Model No (if any)	Intended use	Material of construction	Dimension (if applicable)	Shelf life (if applicable)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) an undertaking from the manufacturer stating that the proposed device is a Class A non-sterile and non-measuring medical device, as per the First Schedule;

(iv) the manufacturer shall self-certify that the product is conforming to the essential principles checklist of safety and performance of such devices;

(v) the manufacturer shall self-certify to comply with the standards specified in these rules; and

(vi) an undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic.

19-I. Registration number.— The registration number for a Class A non-sterile and non-measuring medical device shall be generated after furnishing of the information in accordance with rule 19H on the Online System for Medical Devices established for this purpose.

19J. Import of Class A non-sterile and non-measuring medical device.— (1) Any person who intends to import any Class A non-sterile and non-measuring medical device shall upload the information in sub-rule (2) relating to that medical device for registration on the Online System for Medical Devices.

(2) The importer shall upload the following in the Online System for Medical Devices, namely:—

(i) name and address of importer and the name and address of the manufacturing site;

(ii) details of Class A non-sterile and non-measuring medical devices to be provided:

Generic name	Brand Name (if registered under the Trade Marks Act, 1999)	Model No (if any)	Intended use	Material of construction	Dimension (if applicable)	Shelf life (if applicable)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) an undertaking from the importer stating that the proposed device is Class A non-sterile and non-measuring medical device, as per the First Schedule;

(iv) the importer shall self-certify that the product is conforming to the essential principles checklist of safety and performance of such devices;

(v) the importer shall self-certify to comply with the standards specified in these rules;

(vi) self-attested copy of the overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority or Free Sale Certificate issued by the National Regulatory Authority; and

(vii) an undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.

19K. Registration number for import.— The registration number for import of a class A non-sterile and non-measuring medical device shall be generated after furnishing of the information in accordance with rule 19J on the Online System for Medical Devices established for this purpose.

19L. Maintainance of records.— (1) The manufacturer or, as the case may be, importer shall maintain the records relating to manufacturing or importing along with its sales or distribution.

(2) The manufacturer or, as the case may be, importer shall produce the records, labels, instructions for use, on request by Licensing Authorities.

(3) The Licensing Authorities may verify the records and documents referred to in sub-rule (2) at any point of time and investigate quality or safety related failures or complaints.

19M. Cancellation or suspension of registration.— (1) The State Licensing Authority or the Central Licensing Authority, as the case may be, may, after giving the registrant an opportunity to show cause as to why such an order should not be passed, by an order in writing stating the reasons thereof, cancel the registration number generated under the provisions of rule 19-I or rule 19K, or suspend it for such period as the Licensing Authority thinks fit, either wholly or in respect of any of the medical devices to which it relates, if in its opinion, the registrant has failed to comply with any of the provisions of the rules under this Chapter;

(2) Any person who is aggrieved by an order passed by the State Licensing Authority or the Central Licensing Authority, as the case may be, may, within forty-five days of the receipt of a copy of such order, prefer an appeal to the State Government or the Central Government, as the case may be, and the State Government or the Central Government, shall after giving the said appellant an opportunity of being heard, confirm, reverse or modify such order.**".**

5. In the said rules, in rule 20,—

(a) in the marginal heading, after the word and letter "Class A", the brackets and words "**(other than non-sterile and non-measuring)**" shall be inserted;

(b) after the word and letter "Class A", wherever they occur, the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

6. In the said rules, in rule 31, in sub-rule (1), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

7. In the said rules, in rule 36, in sub-rule (5), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

8. In the said rules, in the Second Schedule, in the table, for the word and letter "Class A", wherever they occur, the words and brackets "Class A (other than non-sterile and non-measuring)" shall be substituted.

9. In the said rules, in the Third Schedule, in Part II, in paragraph 1, in clause (1), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

10. In the said rules, in the Fourth Schedule, in Part II, in paragraph (i), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

11. In the said rules, in the Eighth Schedule, in the table, after serial number 7 and the entries relating thereto, the following shall be inserted, namely:—

S.No.	Class of medical devices	Extent and conditions of exemptions
"8.	Manufacturing of Class A non-sterile and non-measuring medical devices	All provisions of Chapter IV, VII, VIII and XI of these rules, subject to the condition that the manufacturer shall make registration of such devices, under the provisions of Chapter IIIB of these rules.
9.	Import of Class A non-sterile and non-measuring medical devices	All provisions of Chapter V, VII, VIII and XI of these rules, subject to the condition that the importer shall make registration of such devices, under the provisions of Chapter IIIB of these rules.".

12. In the said rules, in the Appendix,—

(a) in Form MD-2, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(b) in Form MD-3, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(c) in Form MD-4, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(d) in Form MD-5, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(e) in Form MD-6, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

[F. No. X.11014/10/2022-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Official Gazette *vide* notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended *vide* notification number G.S.R. 754(E), dated the 30th September, 2022.

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