29.	सीटी स्कैन उपकरण (1 अप्रैल 2021 से प्रभावी)
30.	एमआरआई उपकरण (1 अप्रैल 2021 से प्रभावी)
31.	डीफाइब्रिलेटर्स (1 अप्रैल 2021 से प्रभावी)
32.	पीईटी उपकरण (1 अप्रैल 2021 से प्रभावी)
33.	एक्स-रे मशीन (1 अप्रैल 2021 से प्रभावी)
34.	डायलिसिस मशीन (1 अप्रैल 2021 से प्रभावी)
35.	अस्थि मज्जा कोशिका विभाजक (1 अप्रैल 2021 से प्रभावी)
36.	चिकित्सा युक्ति नियम, 2017 में विनिर्दिष्ट कीटाणुनाशक व कीटनाशक
37.	अल्ट्रासाउंड उपकरण (1 नवंबर 2020 से प्रभावी)

"

[एफ.सं. एक्स.11035/281/2018-डीआरएस]

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. 787(अ), तारीख 16 अक्टूबर, 2019 द्वारा अंतिमतः संशोधित किए गए थे ।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2020

G.S.R. 102 (E).— Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required by under subsection (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. 797 (E), dated the 18th October, 2019, 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 thirty 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 Official Gazette were made available to the public on 18th October, 2019;

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

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (i) These rules may be called the Medical Devices (Amendment) Rules, 2020.

(ii) These rules shall come into force on the 1st day of April, 2020.

2. In the Medical Devices Rules, 2017 (hereinafter to be referred as said rules), after CHAPER III, the following CHAPTER IIIA shall be inserted, namely:—

"CHAPTER IIIA

REGISTRATION OF CERTAIN MEDICAL DEVICES

19A. (1) This Chapter shall be applicable to all devices notified under clause (b) of section 3 of the Act except the medical devices and devices specified in the Annexure of Eighth Schedule of these rules.

(2) The Medical devices referred in sub-rule (1) shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organisation for this purpose:

Provided that registration under this Chapter shall be on voluntary basis for a period of eighteen months from the commencement of this Chapter there after it shall be mandatory.

19B. (1) The manufacturer of a 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" established by the Central Drugs Standard Control Organisation for this purpose

(2) The manufacturer shall upload, -

(i) name & address of the company or firm or any other entity manufacturing the medical device along with name and address of manufacturing site of medical device,

(ii) Details of medical device

Generic Name	Model No.	Intended Use	Class of Medical device	Material of Construction	Dimension (if any)	Shelf Life	Sterile or Non Sterile	Brand Name (if registered under the Trade Marks Act, 1999)

(iii) certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device.

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

19C. After furnishing of the above information on the "Online System for Medical Devices" established by Central Drugs Standard Control Organisation for this purpose by the applicant's, registration number will be generated. Manufacturer shall mention the registration number on the label of the medical device.

19D. (1) Any person who imports any medical device referred in rule 19A shall upload the following information relating to that medical device for registration on the "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation for this purpose.

(2) The importer shall upload, -

(i) name of the company or firm or any other entity importing the medical device and specification and standards of that medical device,

(ii) Details of medical device

Generic Name	Model No.	Intended Use	Class of Medical device	Material of Construction	Dimension (if any)	Shelf Life	Sterile or Non Sterile	Brand Name (if registered under the Trade Marks Act, 1999)

(iii) certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device.

(iv) Free sale certificate from country of origin.

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

19E. After furnishing of the above information on the "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation for this purpose by the applicant's, registration number will be generated. Importer shall mention the registration number on the label of the medical device.

19F. Central Licensing Authority may verify the documents at any point of time and investigate quality or safety related failure or complaints. The Central Licensing Authority 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 therefor, cancel the registration number or suspend it for such period as the Central 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 provision of these rules.

3. In the said rules, in the Eighth Schedule, in the table relating to exemptions, after S.N. 6, the following entry and Annexure shall be inserted, namely:—

"

7	All medical devices except those specified in the Annexure of Eighth Schedule.	All the provisions of these rules subject to the condition that such medical devices shall be registered under CHAPTER IIIA of these rules: Provided that such exemption shall cease after a period of *thirty months* for low risk - Class A and low moderate risk - Class B and after a period of *forty-two months* for moderate high risk – Class C and high risk – Class D devices, respectively from the date of this notification.

Annexure

(See rule 19A)

S. No.	Name of the device
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4.	Substances used for in vitro diagnosis including Blood Grouping Sera
5.	Cardiac Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	I.V. Cannulae
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Devices
16.	Ligatures, Sutures and Staplers
17.	Intra Uterine Devices (Cu-T)
18.	Condoms
19.	Tubal Rings
20.	Surgical Dressings
21.	Umbilical tapes
22.	Blood/Blood Component Bags
23.	Organ Preservative Solution*
24.	Nebulizer (effective from 1 Jan.2021)
25.	Blood Pressure Monitoring Device(effective from 1 Jan.2021)

26.	Glucometer (effective from 1 Jan.2021)
27.	Digital Thermometer (effective from 1 Jan.2021)
28.	All implantable medical devices Equipment (effective from 1, April,2021)
29.	CT Scan Equipment (effective from 1, April,2021)
30.	MRI Equipment (effective from 1, April,2021)
31.	Defibrillators (effective from 1, April,2021)
32.	PET Equipment(effective from 1, April,2021)
33.	X-Ray Machine (effective from 1, April,2021)
34.	Dialysis Machine (effective from 1, April,2021)
35.	Bone marrow cell separator (effective from 1, April,2021)
36.	Disinfectants and insecticide specified in Medical Devices Rules, 2017
37.	Ultrasound equipment (effective from 1, November, 2020)

"

[F.No. X.11035/281/2018-DRS]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The Medical Devices Rules, 2017 was 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. 787(E), dated the 16th October, 2019.

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