Medical Devices Rules, 2017

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The first definition of Medical Devices was introduced in Drugs & Cosmetics Act, 1940 under Section 3(b)(iv) in the year 1982.

Prior to it, there was no definition of Medical Devices.

All devices are covered under section 3(b)(i) of the Drugs Act

e.g.- cotton, bandage, condom and copper wire.

The very first notification of Medical Devices was issued in the year 1989 for the following 03 Medical Devices:

1. Needles
2. Syringes
3. IV sets

Government has notified in-vitro diagnostics devices-

HIV, Hbs Ag & HCV w.e.f. 01.09.2009 as Drug under section 3(b)(i) of the Drugs Act

The following **10** Medical devices were notified as **Medical Devices** in the year **2005** (G.S.R. 627 dated 07.10.2005)

- **Cardiac Stents**
- **Drug Eluting Stents**
- **Catheters**
- **Intra Ocular Lenses**
- **I.V. Cannulae**
- **Bone Cements**
- **Heart Valves**
- **Scalp Vein Set**
- **Orthopedic Implants**
- **Internal Prosthetic Replacements**

Medical Devices Rules, 2017

Medical Devices Rules, 2017 were notified by the Government vide notification no. GSR 78 (E) dated 31.01.2017 which were came into force w.e.f. **01.01.2018.**

MDR, 2017 contains:

12 chapters

08 Schedules

97 Rules

43 Forms.

Definition of Medical Devices under **MDR, 2017 :**

In MDR, 2017 the term ‘medical devices’ is defined under rule **3(zb)**

Medical Devices are classified into 04 classes:

A, B, C & D.

Classification of Medical Devices is based on:

- Involvement of risk of Medical Devices.
- Intended use of such medical devices.

Bio Compatibility

- The word ‘Bio-compatibility’ has been introduced in MDR, 2017. It means property of the material **compatible** with living tissues, should be non-toxic and giving immunological response when exposed to the body.

For Class **A & B** medical devices, licenses are to be issued by **SLA** and for Class **C & D** medical devices, licenses are to issued by **CLA.**

Manufacturer should apply for license application on **Sugam Portal,** designed by **CDSCO office**.

License for **Class A** Medical devices:

No pre inspection is required, SLA will issue the license on Form MD-5.

License for **Class B** Medical devices:

1. Notified body will inspect the premises.
2. SLA will issue the license on Form MD-5.

At present there are **26 notified bodies,** approved by **CLA.**

License for Class **C & D** Medical Devices:

Officers from CDSCO, Delhi will inspect the manufacturing premises and CLA will grant license on MD-9.

Services available on Sugam Portal are:

- Grant of MD manufacturing license.
- Free Sale Certificate.
- Market Standing Certificate.
- Non-Conviction Certificate.
- Loan License.
- Import License.
- Test Permission.
- Clinical Investigation Permission.

Product Standards for Medical Devices:

- As per rule **7** of MDR, **2017.**
- All the products should confirm to the standards prescribed by BIS.
- When there are no standards available for a product then that product shall confirm to the standards prescribed laid down by ISO, IEC or any other Pharmacopoeial standards.
- If no standards are available then inhouse manufacturering standards may be followed.

Labelling of Medical Devices under Rule 44:

- The label of the medical device shall bear expiry date of the product.
- Complete word of ‘expiry’ shall be mentioned on the label.
- The word shelf life can also be used on the label of the medical devices.
- ‘Shelf life’ of the product shall not exceed 60 months.

Repacking of Medical Devices:

- There is no provision for repacking of medical devices under MDR, 2017.

Whether spectacles come under medical devices?

Spectacles are not covered under MDR, 2017.

Contact lenses are notified as medical device under Class-B.

GSR 5980 dated 03.12.2018

Following Medical Devices are notified vide GSR 5980 dated 03.12.2018:

- Nebulizers.
- Blood Pressure Monitoring Devices.
- Digital Thermometers.
- Glucometers.

Govt. notified following Medical Devices vide notification no. **GSR 775 (E) dated 08.02.2019**.

- All implantable medical devices.
- CT Scan Equipment.
- MRI Equipment.
- Defibrillators.
- Dialysis Machine.
- PET Equipment.
- X-Ray Machine.
- Bone marrow cell separator

S.O. No 1500 (E) dated 02.04.2019

Organ preservative solution has been notified as Medical Device vide notification S.O. No. 1500 (E) dated 02.04.2019.

GSR no. 102 (E) dated 11.02.2020 w.e.f. 01.04.2020,

Vide above said notification Govt. has inserted **chapter III A** in the MDR, 2017 in which Government has notified 37 types of Medical Devices under Rule 19 A and has been given time for for voluntary registration of other Medical Devices under Class A, B, C & D.

For Class A & B- 30 months

For Class C & D- 42 months

- Now, from 01 October 2022 onwards voluntary registration period has been finished for Class-A & B Medical Devices and for Class C & D, one more year is there for voluntary registration i.e. upto 31 September 2023.

Broad Definition of Medical Devices

GSR 648 (E) dated 11.02.2020

For Human Beings & Animals w.e.f. 01.04.2020

GSR 777 (E) dated 14.10.2022

For non-measurable and non-sterile **Class A** Medical Devices, no manufacturing license is required. Only registration of the product is required on Sugam Portal.

Non-measurable and non-sterile medical devices covered under **Class A** are exempted under Eighth Schedule of MDR, 2017. It means **no Sale license** is required for selling these drugs/ Medical Devices.

For Non-sterile & Non-measurable medical Devices:

1. No fee is required.
2. No MD form is required to get registration.

Cotton

1. Non-sterile Cotton comes under Class-A of MDR, 2017.
2. No Manufacturing license is required under MDR, 2017.
3. Only registration is required on Sugam Portal.

Sanitary Pad

1. These are not classified as Medical Devices.
2. Hence, no manufacturing/ sale license is required.

DPCO Order, 2013

Four Medical Devices have been **notified as Schedule** Medical Devices.

These are:

- Cardiac Stunt.
- Drug Eluting Stunt.
- Condom.
- Copper T.

Other Medical Devices are non-schedule Medical Devices as per notification no. 1232 (E) dated 31.03.2020 issued by NPPA.

Difference between Drug & Medical Devices:-

- Before MDR, 2017, all medical devices were notified as Drugs.
- 3(b)(i) : Cotton, kits, bandages, etc.
- 3(b)(ii): Condom, Copper T, etc.
- 3(b)(iv): Syringes, Stunts, IV Cannula, etc.
- Now, definition of Medical Devices has been given in MDR, 2017 under Rule 3 (ZB).
- In MDR, 2017, word 'QMS' introduced instead of previously used word 'GMP'.
- Previously License was issued on Form-25 & 28, now it is issued on Form- MD5 & MD6.

Rule 27 of MDR, 2017:

Change in Constitution:

- Manufacturers should inform the authorities within 45 days.
- Application should be given within 06 months of such change.

Qualification of Technical Staff:

Rule 22 of MDR, 2017

- Education Qualification of Manufacturing Chemist & Analytical Chemist with experience is mentioned in above said rule.

Fee structure

For Class-A & B

Sr. No.	Subject	Fee in Rs.
1.	Manufacturing license	5000
2.	Additional product (each)	500
3.	Test License	500
4.	Free Sale Certificate	1000

Fee Structure

For Class-C & D

Sr. No.	Subject	Fee in Rs.
1.	Manufacturing license	50000
2.	Additional product (each)	1000
3.	Test License	500
4.	Free Sale Certificate	1000

QMS (Quality Management System) Certificate

Now, in MDR 2017, there is provision of QMS certificate just like GMP certificate as issued for Allopathic Drug Manufacturing units.

Medical Devices manufacturing firms has to comply with the conditions mentioned in fifth Schedule of MDR, 2017.

Commonly Used Medical Devices with their Class:

Sr. No.	Medical Devices	Class
1.	Cotton	A
2.	VTM Kit	A
3.	Blood Bag	C
4.	Disinfectant	B
5.	Cotton Crepe Bandage	A
6.	Surgical Gown (Non-sterile)	A
7.	Surgical Gown (Sterile)	B
8.	Face Shield	A
9.	Blood Collection Tube	A
10.	IV Cannula	B
11.	Contact Lenses	B

Rule 45 of MDR, 2017

Special & Code Neutral

This certificate is to be issued approved by **CLA** for **Class A, B, C & D, where it is required.**

Rule **31** of MDR, 2017

Test license

This license is issued by **CLA** for Class A, B, C & D on Form-MD 13 for 03 years.

COPP

There is no provision of COPP under MDR, 2017.

Metrology: Legal Metrology Rules, 2011

- Medical Devices are not exempted.
- As per Rule 26 C, all the scheduled drugs and non scheduled drugs are exempted from this Act but not medical devices.

Example:

- Suppose a firm is having license on Form-28, valid up to 31.12.2022 for manufacturing, Haemodialysis Concentrate.
- Now, this product comes under MDR , 2017 as Class C.
- So, manufacturing firm should apply for the conversion of license from Form-28 to MD-9, before expiry of old license i.e. 31.12.2022 and should also get the new license before 31.12.2022.

Central Medical Testing Laboratories for the purpose of functioning as Appellate Laboratory:

1. The National Institute of Biological, Noida.
2. The Central Drug Testing Laboratory, Chennai.
3. The Central Drug Laboratory, Calcutta.
4. The Regional Drug Testing Laboratory, Guwahati.
5. The Central Drug Testing Laboratory, Mumbai.
6. The Regional Drug Testing Laboratory, Chandigarh.

S.O. No. 2237 (E) dated 01.06.2018

S.O. No. 4573 (E) dated 28.09.2022

All these labs are specially assigned for the testing of specific categories of Medical Devices.

GSR 754 E dated 30 September 2022.

For Sale of Medical Devices.

Application for registration is to be submitted on Form-MD 41.

Following are the Conditions of registration:

- Fee-3000/-
- Self declaration on undertaking certificate w.r.t. good distribution compliance.
- Constitution of the firm with Aadhaar card of proprietor/ partner/ director.
- Affidavit in respect to the ownership of the premises.

- Details of technical person (Graduate or Registered Pharmacist, or intermediate with one year experience).
- Undertaking regarding the storage of Medical Devices.
- Brief description on activity carried out by the applicant about the storage of Medical Devices.

- Registration certificate to be issued within 10 days.
- Record to be maintained by the firm for 02 years.
- Validity of registration certificate is for 05 years.
- No renewal only Retention.

- If a chemist having license under Drugs & Cosmetics Act (on Form-20/21 & Form-20 B/21 B then
- No separate registration for sale of Medical Devices license is required as per Rule 87 of MDR, 2017.

Sale of all the medical devices i.e. A, B, C & D.

Only one registration certificate is required i.e. Form-42.

But for medical devices covered under Class C & D.

Registration time has been increased upto October, 2023 (except 37 categories of medical devices mentioned in rule 19 A of the MDR).

Important Notifications under MDR, 2017

Sr. No.	Subject	GSR No.	Date	Effective Date
1.	Definition of Medical Devices		13.11.1982	
2.	03 MD items	365 (E)	17.03.1989	17.03.1989
3.	HIV Kits	601 (E)	27.08.2002	01.09.2002
4.	Old Notification for 10 products	627	07.10.2005	07.10.2005
5.	MD Rules	78 (E)	31.01.2017	01.01.2018
6.	4 MD Items	5980 (E)	03.12.2018	01.07.2021
7.	8 Items	775 (E)	08.02.2019	01.07.2022
8.	Free Sale Certificate	318 (E)	18.04.2019	18.04.2019

Sr. No.	Subject	GSR No.	Date	Effective Date
9.	Organ Preservative solution	1500 (E)	02.07.2019	02.07.2019
10.	Ultrasound	S.O. 3721(E)	16.10.2019	01.11.2020
11.	Definition of MD	648 (E)	11.02.2020	01.04.2020
12.	Amendment in Rule 19 (A)	102 (E)	11.02.2020	01.04.2020
13.	Medical Devices under DPCO	1232(E)	31.03.2020	01.04.2020
14.	Unique device	918 (E)	31.12.2021	01.01.2022
15.	Sale of Medical Devices	754 (E)	30.09.2022	30.09.2022
16.	Registration License for Class A	777 (E)	14.10.2022	14.10.2022

24 Medical Devices Categories

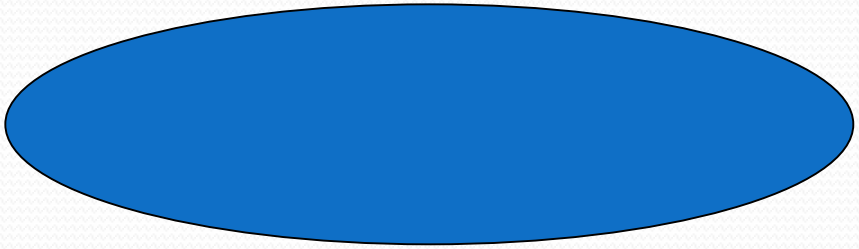
Sr. No.	Date of DCGI letter under Rule 4 MDR, 2017	Category of Medical Devices	Number of items as per DCGI letter
1.	12 July 2021	Anesthesiology	112
2.	23 July 2021	Software	60
3.	26 July 2021	Cardiovascular	36
4.	26 July 2021	Physical Support	38
5.	26 July 2021	Radiology	66
6.	06 Aug 2021	Dermatological/ Plastic Surgery	55
7.	06 Aug 2021	ENT	67
8.	06 Aug 2021	Radiotherapy	101

24 Medical Devices Categories

Sr. No.	Date of DCGI letter under Rule 4 MDR, 2017	Category of Medical Devices	Number of items as per DCGI letter
9.	06 Aug 2021	Respiratory	51
10.	19 Aug 2021	Ophthalmology	135
11.	10 October 2022	Dental	95
12.	23 Aug 2021	Pediatrics and neonatology	136
13.	23 Aug 2021	Urology	88
14.	27 Sept 2021	Neurological	110
15.	13 Sept 2021	Personal Protective Equipment	32
16.	13 September 2021	Nephrology and Renal Care	44

24 Medical Devices Categories

Sr. No.	Date of DCGI letter under Rule 4 MDR, 2017	Category of Medical Devices	Number of items as per DCGI letter
17.	13 September 2021	Operation Theatre	26
18.	13 September 2021	Pain Management	26
19.	27 September 2021	Gastroenterology	153
20.	11 October 2022	Oncology	48
21.	16 March 2022	General Hospital/ Orthopaedic inst.	146
22.	03 June 2022	Obstetrical and Gynecological	123
23.	04 Aug 2022	Rehabilitation	60
24.		Rheumatology	



Thank You !!!