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 first notification for Medical Devices was issued in the year 1989 by which following 03 Devices were notified:

1. Needles
2. Syringes
3. IV sets

Government has notified in-vitro diagnostics devices for **HIV, HbsAg & HCV w.e.f. 01.09.2002 as Drug under section 3(b)(i) of the Drugs Act**

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 Sets**
- **Orthopaedic 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 have been enforced 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 device’ is defined under rule **3(zb)**

Medical Devices have been classified into 04 classes:

A, B, C & D.

Classification of Medical Devices is based on:

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

Bio Compatibility

- The word ‘Biocompatibility’ 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.**
- For Class **C & D** Medical Devices, licenses are to be issued by **CLA.**

Manufacturer has to apply on **Sugam Portal**, developed by **CDSCO to obtain license to manufacture Medical Devcie(s).**

License for **Class A** Medical Devices:

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

or

- License on Form MD-5 will be issued by SLA.

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 of CDSCO, New Delhi will inspect the manufacturing premises and CLA will grant license on Form MD-9.

Services available on Sugam Portal are:

- 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 conform to the standards prescribed by BIS.
- If no BIS standard is available for a product then that product should conform to the standards prescribed by ISO, IEC or any other Pharmacopoeial standards.
- If no standards as mentioned above are available then inhouse manufacturing standards may be followed.

Labelling of Medical Devices under Rule 44:

- The label of the medical device should bear expiry date of the product.
- Complete word like ‘expiry’ should be mentioned on the label short for e.g. Exp. Cannot be used.
- If the product applied is sterile, then manufacturing should have facility to sterile that product.

- The word ‘shelf life’ can also be used on the label of the Medical Devices.
- ‘Shelf life’ of the product should not exceed 60 months.
- Permission can be given by Generic & Brand name.
- Generic name and intended use on the label should be same as mentioned in the notified MD list.

- If a firm is manufacturing both Medical Devices & IVD, then the firm will get separate license number for Medical Devices and IVDs.

- E.g. If a firm is manufacturing cotton as well as testing kit, then the firm will have to get two different licenses.

Repacking of Medical Devices:

- There is no provision for repacking of Medical Devices in MDR, 2017.

Spectacles

‘Spectacles’ are not covered under MDR, 2017.

but

‘Contact lenses’ are notified as Medical Device under MDR, 2017 & classified as Class B Medical Device.

GSR 5980 dated 03.12.2018

Following Medical Devices were notified vide GSR 5980 dated 03.12.2018:

- Nebulizer.
- Blood Pressure Monitoring Devices.
- Digital Thermometer.
- Glucometer.

Following Medical Devices have been notified 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 this notification, Govt. has inserted **chapter III A** in MDR, 2017 by which Government has notified 37 types of Medical Devices under Rule 19 A Govt. has given time for voluntary registration of other Medical Devices of Class A, B, C & D as under.

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.
- For Class C & D, voluntary registration can be done till 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 (cdscomdonline.gov.in)

Non-measurable and Non-sterile Medical Devices

These 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.

Non-measurable & For Non-sterile Medical Devices:

1. No fee is required for regsitration.
2. No MD form is required for registration.

Cotton

1. Non-sterile Cotton classified as Class-A under MDR, 2017.
2. No Manufacturing license is required under MDR, 2017 for it.
3. Only registration is required on Sugam Portal.
4. Date of registration May 2019 at Serial No. 31?

Sanitary Pads

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

Bandages

1. All bandages with cloth material are available in market are notified as medical devices of Class B.
2. Crepe bandages and tapes come under Class A.

Blood bag

1. It is a Medical Device.
2. It should be tested by an approved lab having Medical Device Testing License or resgistration and report of test will be issued on **Form MD-32.**

Status of Oxygen Concentrator

- This is notified as Medical Device.
- Classified as Class-C.
- It is a non-schedule drug.
- Price has to be fixed by NPPA.

Private Testing Registration to the lab

1. It is to be issued by the O/o DCGI , New Delhi.

Clinical Chemistry Analyser

1. This is a Class A Medical Device.
2. Intended use is qualitative and quantitative.
3. It means it is measurable.
4. Hence, it requires a license.

Breast Pumps

Till date not regulated as Medical Device.

Example

Suppose a firm is having license for manufacturing Class A & B Medical Devices and wants to manufacture Medical Devices of Class A, Non-sterile & Non-measurable

In that Case, firm may be asked to apply on sugam portal for registration of those Medical Devices.

DPCO Order, 2013

Four Medical Devices have been **notified as Scheduled** Medical Devices, which 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.

Before and after introduction of Medical Devices, 2017:-

- Before MDR, 2017, all Medical Devices were notified as Drug.
- 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'.
- Before MDR, 2017 License was issued on Form-25 & 28, now it is issued on Form-MD5 & MD6.

Change in Constitution:

Rule 27 of MDR, 2017:

- Manufacturers should inform the licensing authority within 45 days of change and application should be submitted within 06 months of such change.

Rule 22 of MDR, 2017

Qualification of Technical Staff:

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

Fee structure

For Class-A & B Medical Devices

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

Fee Structure

For Class-C & D Medical Devices

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 to Allopathic Drug Manufacturing units.

Medical Devices manufacturing firms has to comply with the conditions for QMS 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

Commonly Used Medical Devices with their Class:

Sr. No.	Medical Devices	Class
1.	Latex examination gloves	A
2.	Patient gown	A
3.	Surgical Cap	A
4.	PPE Kit	B
5.	Latex surgical gloves	B
6.		
7.		
8.		
9.		
10.		
11.		

Rule 45 of MDR, 2017

Code Number/ Special Code Number/ Neutral Code

This code/certificate is to be issued/ approved by **CLA** for **Class A, B, C & D or all Medical Devices if applied by manufacturers.**

Sections of Show Cause Notice

Rule 30 (1) of Medical Devices Rules, 2017

Or

Show Cause Notice to Medical Devices manufacturer, whenever required is issued u/r 30(1) of MDR, 2017.

Test license

Rule **31** of MDR, 2017

It is issued by **CLA** for Class A, B, C & D Medical Devices on Form-MD 13 valid for 03 years from the date of its issuance.

COPP

There is no provision for COPP under MDR, 2017.

Legal Metrology Rules, 2011

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

Example:

- Suppose a firm is having manufacturing license on Form 28, valid up to 31.12.2022 for the product Haemodialysis Concentrate.
- Now, this product has been classified as Class C under MDR , 2017.
- 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 designated as Appellate Laboratories:

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 30th September 2022.

For Sale of Medical Devices.

Conditions for Registration for sale of Medical Devices:

- Application for registration is to be submitted on Form-MD 41.
- Fee-3000/-
- Affidavit regarding ownership of the premises or rent deed.
- Self declaration or undertaking w.r.t. Good Distribution compliance.

- 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.
- Self declaration/ undertaking for :

  - GDC

  -Storage of Medical Devices

- Registration Certificate to be issued within 10 days.
- Sale record to be maintained by the firm for 02 years.
- Validity of registration certificate is for 05 years from the date of registration.
- No Renewal only Retention of certificate.

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

Rule 88

Supply of Medical Devices to Hospital

- Any MD licensee firm can supply medical devices to a hospital for its patient against delivery challan.
- Cash memo shall be generated for such medical devices by the licensee as per condition of license.

For import of Medical Devices

Import license is mandatory.

For sale of Medical Devices of A, B, C & D Classes

- Only one registration certificate is required i.e. Form-42.
- For medical devices covered under Class C & D, time for voluntary registration has been extended 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 Categories of Medical Devices

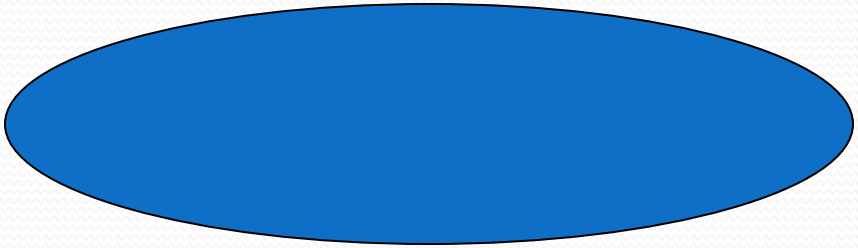
Sr. No.	Date of DCGI letter under Rule 4 MDR, 2017	Category of Medical Devices	Number of items as per DCGI letter
1.	12 July 2021	Anesthesiology	112
2.	23 July 2021	Software	60
3.	26 July 2021	Cardiovascular	36
4.	26 July 2021	Physical Support	38
5.	26 July 2021	Radiology	66
6.	06 Aug 2021	Dermatological/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