Medical Device Legislation in India

(Requirement for grant of import/manufacturing license/permissions)

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Content

- Overview of Medical Device Industry in India
- Regulatory Framework for Medical Devices
- Requirements for Manufacturing of Medical Devices
- Requirements for Import of Medical Devices
- Requirements for Investigational Medical Devices

Overview of Medical Device Industry in India

- **Market Size- USD 11 billion in 2020 and expected to grow to 50 Billion by 2030.**
- **India is the 4th largest Asian medical devices market and among the top 20 medical devices markets globally.**
- **Highest growth potential among all sectors in healthcare market (Expected growth rate of 14% as per CAGR)**
- **Major manufacturing in the country is happening w.r.t : *Disposables, Implants & IVDs***
- **India depends on imports (upto 80% by value) of its domestic requirements.**

Medical Devices Regulatory Framework

- **Drugs & Cosmetics Act, 1940, a Central Act enforced by both Central and State Governments. Extended to Whole of India**
- **The objective of the Act is to regulate :**
  - **Import, Manufacture**
  - **Sale and Distribution of drugs and cosmetics**
- **Presently, under the said Act, Medical Devices (MD) are defined under definition of 'Drugs'.**

Genesis of MDR 2017

- Only certain medical devices are regulated. Underdeveloped regulatory framework. Medical Devices are regulated as “Drugs”. No specific requirements for import, manufacture, clinical investigation etc. for medical devices in the law.

- The lack of proper regulatory systems, harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices etc. are affecting the medical devices industry adversely.

- In order to have specific requirements for medical devices, Medical Device Rules, 2017 have been published under the said Act, wherein the requirements for import, manufacture, clinical investigation, sale and distribution of medical devices have been prescribed in Medical Device Rules, 2017. Theses new Rules have been implemented from 1st January, 2018.

History of Medical Devices Regulations:

1 MD Notified U/s 3b(ii) of the Act	1961
Definition of “Device” is included in the Act	Feb 1983
Initially 3 devices are notified as Drugs	March,1989
Schedule M-III	Feb 1994
4 IVDs Notified	August 2002
10 MD Notified	October 2005
1 MD Notified.	January, 2016
SCHEDULE M-III Quality Management System	29.06.2016
Medical Device Rule, 2017 w.e.f. 1.01.2018	31.01.2017
4 MD notified.	03.12.2018
8 MD notified.	08.02.2019
1 MD Notified	02.04.2019
1 MD Notified.	16.10.2019
The MOH&FW notified the devices definition U/s 3b(iv) of the Act	11.02.2020

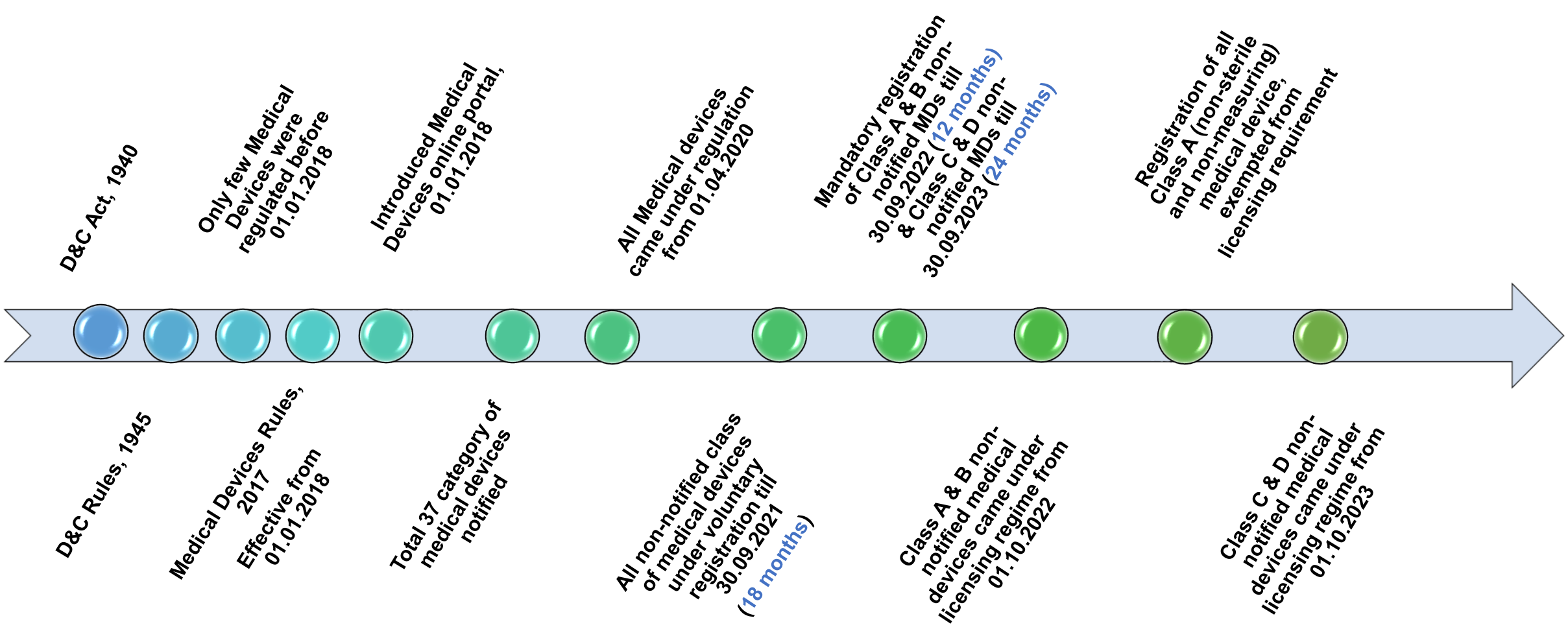
Notified Definition :

The MOH&FW notify vide S.O. 648(E) dated 11.02.2020 specifies the following devices intended for use in human beings or animals as drugs with effect from the **01.04.2020**

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

- **diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;**
- **diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;**
- **investigation, replacement or modification or support of the anatomy or of a physiological process;**
- **supporting or sustaining life;**
- **disinfection of medical devices; and**
- **control of conception.**

Medical Devices Regulation Road map in India



Medical devices Rules, 2017:

Summary:

Chapters: 12

Rules: 97

Schedule: 8

Forms: 43

Medical Devices Rules, 2017- Chapters

Chapter- I	Title, Application, Commencement, Definition
Chapter - II	Classification of MD, Grouping of MD, Essentials Principles
Chapter - III	Authorities, delegation of powers, Notified bodies, Medical Devices Testing Centres,
Chapter - IV	Manufacture of MD-Application, Inspection, grant of lic, conditions of lic, Suspension, Cancellation, Appeal, Test License
Chapter - V	Import of MD-Application, Overseas Inspection, grant of lic, Test lic, Hospital use, Personal use
Chapter - VI	Labelling requirement
Chapter - VII	Clinical Investigation- Permission, Medical management, Compensation, Inspection
Chapter - VIII	Permission to import or manufacture medical device which does not have predicate medical device
Chapter -IX	Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body
Chapter -X	Registration of Laboratories for carrying test or evaluation on behalf of manufacturer
Chapter - XI	Sale of Medical Devices
Chapter - XII	Miscellaneous – Rejection of application, Debarment of applicant, Exemptions

Medical Devices Rules, 2017: Schedules

Schedule	Title
First	Parameters for classification of medical devices & in vitro diagnostic medical devices
Second	Fee payable for licence, permission and Registration Certificate
Third	Documents required for Registration of notified body, its duties and functions.
Fourth	Documents required for grant of licence to manufacture for sale or for distribution or import
Fifth	Quality management system for manufacturing of medical devices & in vitro diagnostic medical devices.
Sixth	Post approval changes: Major & Minor changes
Seventh	Requirements for permission to import or manufacture investigational medical device for conducting clinical investigation.
Eighth	**Exemptions-** • Custom made devices are exempted from provisions of import and manufacture. • Medicated Dressings and bandages, mechanical contraceptives etc are exempted from provisions of Sale. • Devices intended for charity – exempted from import licence

Risk based classification

- **Medical devices notified by MOH&FW, GOI shall be classified by the Central Government based on the classification rules specified in the First Schedule of the Medical Device Rules, 2017.**
- **All Notified Medical Devices have been classified as per their risk profile. Following are the risk classes and the classification criteria based on the severity of risk associated with the medical device .**

Risk Criteria	Risk Class
Low	Class A
Low-Moderate	Class B
Moderate-High	Class C
High	Class D

Regulatory Authorities

Device Class Activity	Class A	Class B	Class C	Class D
Import	CLA	CLA	CLA	CLA
Manufacture	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
Sale	SLA			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA
*Note: Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.				

Notified Bodies- Registration & Scope

- **Registered with CDSCO**
- **Accredited by National Accredited Body [such as NABCB (National Accreditation Board for Certification Bodies), Quality Council of India)**
- **Procedures prescribed in schedules for registration of notified bodies**
- **Duties, functions and obligations of notified bodies specified in the *Third Schedule* of the rules**

SCOPE:

- **Only Class A and Class B Medical Devices/IVDs**
- **To verify QMS conformance at manufacturing site**
- **Verification of Essential Requirements**
- **Verifying validation of manufacturing process through objective evidence**
- **Conformity of material with defined specifications**

Standards of Medical Devices

- **Product Standards -** As per Rule 7, the medical device shall conform to the standards laid down by the Bureau of Indian Standards. Where no relevant Standard of any medical device has been laid down by the Bureau of Indian Standards, such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

  In case of the standards which have not been as specified neither by BIS nor by ISO/IEC, the device shall conform to the validated manufacturer's standards.

- **Process Standards -** Under Rule 6- Essential principles of Safety and performance for the indications for which the medical device is claimed.

Relevant Chapters and Rules

Chapter	Title	Applicable Rules
Chapter IV	Manufacturing	Rule 20 to Rule 33
Chapter V	Import	Rule 34 to Rule 43
Chapter VI	Labelling	Rule 44 to Rule 48
Chapter VII	Clinical Investigation	Rule 49 to Rule 62
Chapter VIII	Permission for Investigational medical device	Rule 63 to Rule 65

Flow chart for grant of manufacturing license of Medical Devices for marketing

Application in requisite Form **(Form MD-3/MD-4/MD-7/MD-8**) shall be submitted to the licensing Authority (LA) concerned along with requisite fees, Plant Master File, Device Master File including other technical documents as prescribed in the Fourth Schedule (Part II) of MDR-2017

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After satisfactory scrutiny of the documents, QMS inspection of the site shall be carried out by Medical Device Officers (MDOs)/ NOTIFIED BODY

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Based on the satisfactory QMS compliance report, the application is referred to the Licensing Authority for approval

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After satisfactory requirement, a License is granted by Licensing authority in Form **(Form MD-5/MD-6/MD-9/MD-10)**

Legal and Technical document:

- device description, intended use of the device, specification including variants and accessories;
- working principle and use of a novel technology (if any);
- labels, package inserts
- constitution details of the firm
- EP checklist
- Undertaking for compliance of QMS from the manufacturer

Note:

1. Incase of Investigational Medical device, the applicant need to obtain prior permission from CLA in Form MD-27 under MDR-2017

2.Class A (non-sterile and non-measuring) medical devices are exempted from the License requirements, however the manufacturer shall register such device in the MD online portal of CDSCO for obtaining Registration number and comply with the labelling requirements as per MDR for marketing in the country.

Approval process for Import license of Medical Devices for marketing

Application shall be submitted in Form **MD-14** along with requisite fees, Plant Master File, Device Master File including other legal and technical documents as prescribed in the Fourth Schedule (Part II) of MDR-2017 to the Central Licensing authority (CDSCO (HQ))

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Scrutiny of the documents by the CDSCO (HQ)

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If the documents are found satisfactory, then License is granted by Central Licensing authority in Form **MD-15** (import license)

Legal and Technical document:

- Power of Attorney from the foreign manufacturer
- Free Sale Certificate, Quality certificate and other regulatory certificate of the devices from the foreign manufacturer
- device description, intended use of the device, specification including variants and accessories;
- working principle and use of a novel technology (if any);
- labels, package inserts
- constitution details of the firm
- EP checklist
- Undertaking for compliance of QMS from the manufacturer
- Performance evaluation report in case of IVDs
- *Device Master File is not mandatory for Class A medical devices

Note:

1. ***In case of Investigational Medical device, the applicant need to obtain prior permission from CLA in Form MD-27 under MDR-2017***
2. ***Class A (non-sterile and non-measuring) medical devices are exempted from the License requirements, however the manufacturer shall register such device in the MD online portal of CDSCO for obtaining Registration number and comply with the labelling requirements as per MDR for marketing in the country.***
3. ***Central Licensing Authority, may cause an inspection of the overseas manufacturing site (if required) for which the applicant shall be liable to pay a fee in respect of expenditure required overseas manufacturing site inspection.***

Permission to manufacture/import of Investigational Medical Devices

Application shall be submitted in **Form MD-22** along with requisite fees, Clinical Investigation Plan, technical documents as prescribed in the Seventh Schedule of MDR-2017 to the Central Licensing authority

Technical document:

- Technical dossier of the device.
- QC, stability, validation, Pre-clinical study results, etc
- Clinical Investigation Plan for approval for Pilot/Pivotal Study to generate Clinical data on Indian population (human subjects)

After satisfactory scrutiny of the documents and recommendations from Subject Expert committee (SEC) the Permission is granted by Central Licensing Authority for Conduct of Clinical Investigation in **Form MD-23** to generate the Clinical data on the Indian population

Thereafter, an application shall be submitted in **Form MD-26** (manufacturing/import) along with requisite fees, Clinical Investigation report, technical documents as prescribed in the Fourth Schedule (Part IV) of MDR-2017 to the Central Licensing authority

Technical document:

- Device Master file of the device.
- Submit the data related to Clinical evidence, Validation, etc.

After satisfactory scrutiny of the documents and recommendations from Subject Expert committee (SEC) the Permission is granted by Central Licensing Authority for manufacture/import of Medical Device (which does not have predicate device) in **Form MD-27**

Note: # Ce***ntral Licensing Authority, in public interest, abbreviate, defer, or waive the requirements of conducting Clinical Investigation in case of life threatening, serious diseases or diseases of special relevance to the Indian health scenario, national emergencies, extreme urgency, epidemic and medical devices indicated for conditions, diseases for which there is no therapy.***

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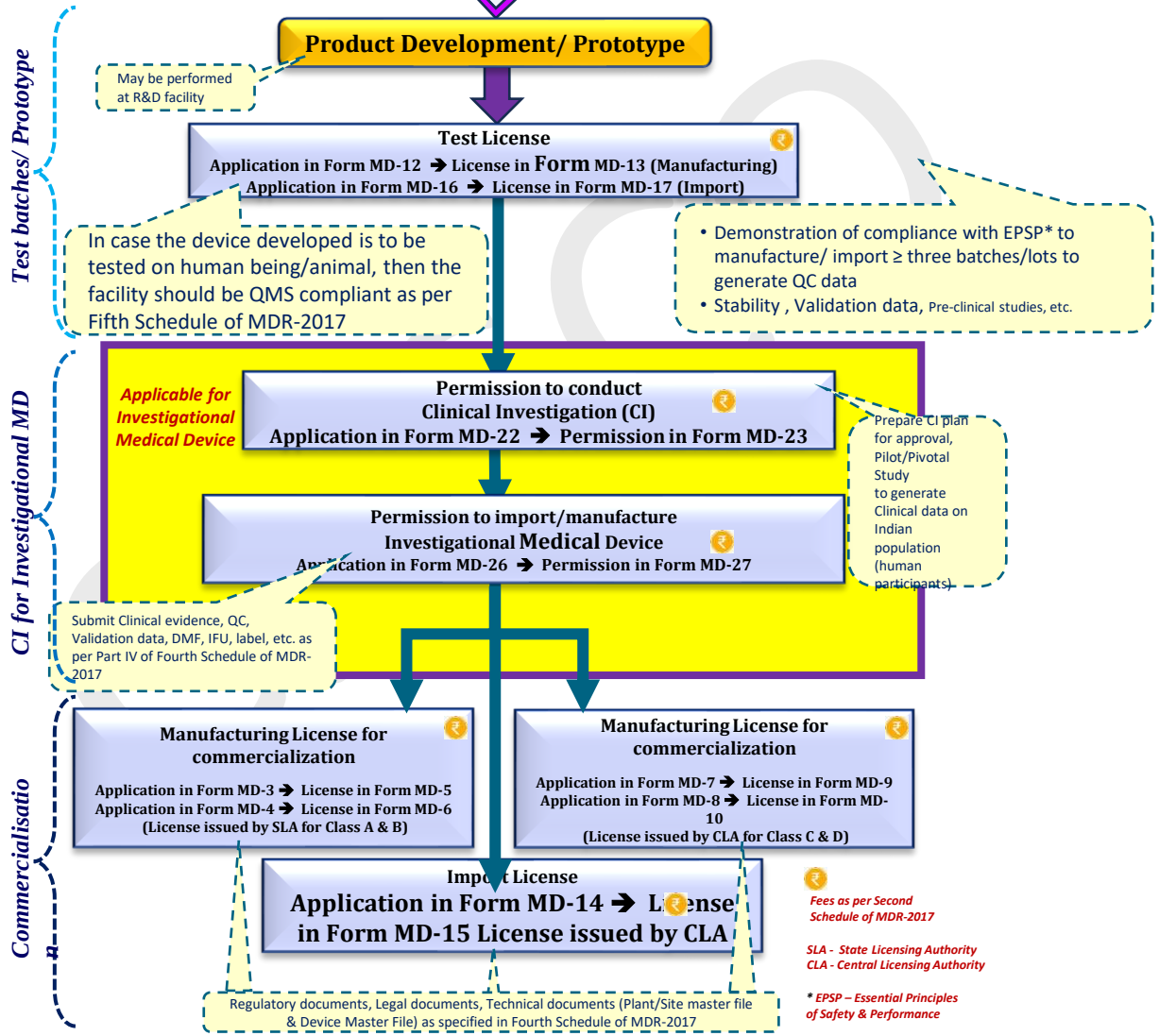
Clinical investigation may be exempted/ abbreviated where the investigational medical device is approved by the regulatory authorities of UK/USA/Japan/Australia/Canada or Japan provided the said device has been marketed for at least two years in that country and the Central Licensing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device.

Regulatory pathway for Startups/Innovators/Manufacturer for commercialisation of Medical Devices under Medical Devices Rules, 2017



NOTE: # Class A (Non-sterile & non-measuring) Medical Devices exempted ## CI for Class A Medical not mandatory

All applications shall be submitted through Medical Devices online portal (www.cdscomdonline.gov.in)

Notified Bodies and Laboratories

- **Notified body is required to be registered with CDSCO.**
- **At present 14 Notified Bodies are registered with CDSCO.**
- **06 Central Medical Device Testing Laboratories (CMDTL) are notified for statuary testing**
- **53 Medical Devices Testing laboratories (MDTL) are registered to carry out testing or evaluation of a medical device on behalf of a manufacturer under Medical Device Rule, 2017**

Guidance, FAQ etc. on MDR, 2017

- **Classification List of medical devices is published. The list is dynamic and is subjected to revision from time to time.**
- **Grouping guidelines for medical devices.**
- **Guidelines on Essential Principles for safety and performance of Medical Devices**
- **Medical Device Adverse Event reporting form**
- **Frequently Asked Questions (FAQ) on Medical Device Rules, 2017.**
- **Guidance document on Essential Principles on Safety and Performance of Medical Devices.**
- **Guidance document on Free Sale Certificate/Marketing Standing Certificate/Non-conviction certificate.**

THE ‘DRUGS, MEDICAL DEVICES AND COSMETICS BILL, 2023’

- **THE DRAFT ‘DRUGS, MEDICAL DEVICES AND COSMETICS BILL, 2022’**
- **Some of the notable amendments/ provisions of this Bill are listed below:**
- **The government in the Draft Bill has adopted the Internationally harmonized definition of medical devices**
- **Establishment of regulatory bodies associated with CDSCO such as Ethics Committee, Medical Devices Technical Advisory Board (MDTAB), and a Consultative Committee to advise the Central Government and State Governments on technical matters pertaining to medical devices, and to ensure responsible overseeing of the trials to be formed.**
- **Rules pertaining to conducting clinical trials of medical devices have been developed to safeguard the rights, safety and well-being of all trial participants.**
- **Strict legal action/ punishment and penalties have also been introduced for conducting clinical trials without permission or following protocol and manufacturing or sale of spurious/ adulterated/ misbranded medical devices.**

Website: cdsco.gov.in

Thank you for your kind attention…