India Medical Device Rules, 2017

An overview of the regulatory framework

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Introduction

India has made significant strides in the healthcare sector in recent decades. This is reflected in the progress being made towards lower national maternal mortality rates (MMR), infant mortality rates (IMR), total fertility rates and **other key public health indicators**. Medical device technologies, through their disruptive solutions, have the potential to provide the impetus needed to make the healthcare system more accessible, affordable and sustainable going forward.

The global medical device market is poised to grow at a compound annual growth rate (CAGR) of 9.21% between 2020 and 2030 and is projected to grow from $515 billion (USD) in 2020 to USD $1.243 trillion (USD) by 2030. The Indian medical device market is estimated at $11 billion (USD) and is expected to grow to $50 billion (USD) by 2030 with CAGR of 16.4%., and with a market share estimated to be 1.65% of the global medical devices market.

Under the India Vision 2047, the Indian government aims to have a strong, fair, competitive and green industry that derives its strength from a wide variety of disciples. Those include: the digital transformation of healthcare, well-functioning integrated supply chains and an approach that caters to medical devices, from production to distribution, consumption and disposal. This must all be done in a responsible manner with ambitious objectives, including, but not limited to establishing 50 medical devices clusters/ parks, focusing on AI and ML in the medical devices sector, introducing an innovative pricing framework. Once accomplished, this endeavor willposition India as an originator of technology such as robotics, 4D, organ bioprinting, laser physics and more.

Currently, India is counted among the top 20 global medical device markets and is the **fourth largest medical device market in Asia** after Japan, China and South Korea.

The Indian government has taken some early steps to boost this sunrise segment in the country, including:

- Permitting 100% automatic foreign direct investment (FDI) in the sector, helping attract FDI worth $1.57 billion (USD) from April 2000 to March 2017
- Strengthening the medical device sector as part of the Make in India initiative that provides immense opportunities to global companies, local manufacturers and startups
- Rolling back import duty concessions for 67 medical devices
- Establishing two flagship schemes – Production Linked Incentives (PLI) scheme and Medical Device Park across the country

The Central Drugs Standard Control Organization (CDSCO) authorized by the Directorate General of Health Services within the Ministry of Health and Family Welfare (MoHFW), regulates the medical device industry.

The Drugs and Cosmetics Act of 1940 (D&C Act) and the Drugs and Cosmetics Rules of 1945 govern the medical device industry in India, along with the **Medical Device Rules, 2017** and the Medical Devices (Amendment) Rules of 2020. In July 2022, the MoHFW unveiled a draft New Drugs, Medical Devices and Cosmetics Bill, to keep pace with changing needs, times and technology. In May 2023, the government of India introduced the National Medical Device Policy, with the goals of achieving universal access to quality medical devices; boosting domestic manufacturing capacity for affordability; enhancing product quality and global competitiveness; improving clinical outcomes through early diagnosis and accurate treatment; promoting a healthier lifestyle through extensive device applications; fostering innovation in the sector; and developing strong local manufacturing capabilities and resilient supply chains.

While complementing the D&C Act, the Medical Device Rules 2017 specifically included the following major changes:

- New rules-based classification system for medical devices and IVDs
- Rules defining medical devices, active medical devices, active diagnostic medical devices, active therapeutic medical devices, etc.
- All IVD kits/reagents are subject to registration requirements. The following types of IVDs i.e. serodiagnostic test kits for diagnosis of tuberculosis and antibody detecting rapid diagnostic tests for routine diagnosis of malaria are prohibited in India
- Licenses issued to device registrants would remain valid indefinitely, along with payment of license retention fees, unless canceled or surrendered
- The rules include fee revisions based on device classification with an overall increase in application fees
- Product standards for medical devices
- Device manufacturing sites in India must undergo audits by Notified Bodies to obtain manufacturing licenses
- Foreign manufacturing sites may be subject to inspection by India's Central Licensing Authority
- Consolidation of registration certificate and import license
- New regulatory framework for clinical investigation of medical devices
- Indian regulators will require unique device identification (UDI) of medical devices and IVDs with effect from the date as may be specified by CDSCO
- Application for test licenses need to be submitted under the National Single Window System (NSWS) portal and will remain valid for three years

The Medical Device Rules, 2017 also rely heavily on the **SUGAM online portal**, which is used for all medical device/IVD regulatory submissions in India.

The overall regulatory process for marketing medical devices/IVDs in India is summarized in the figure below:

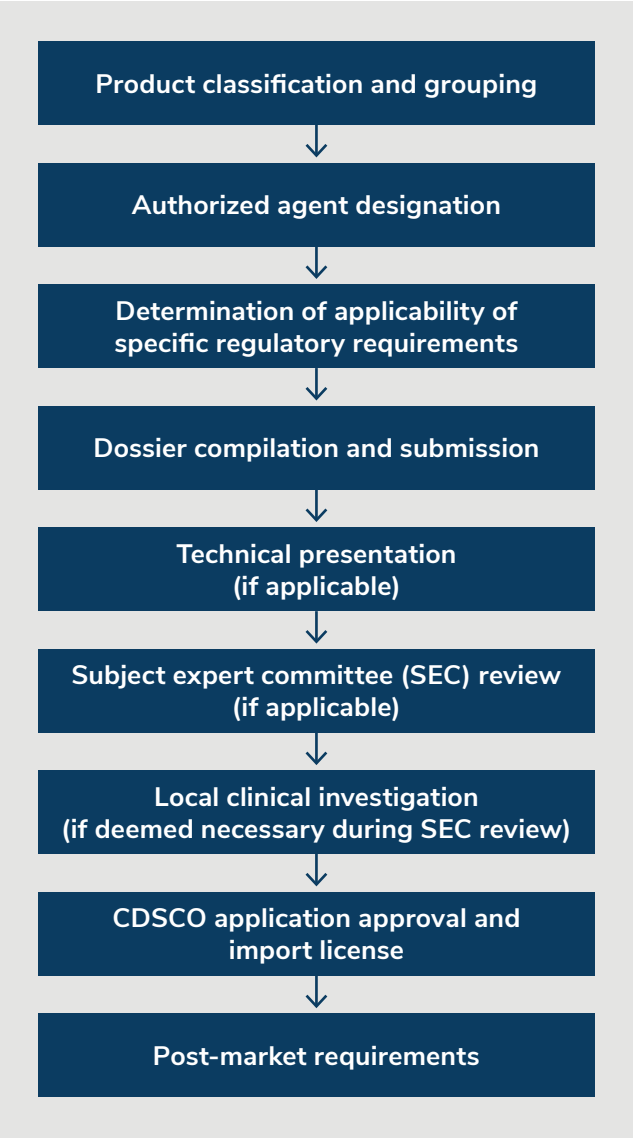

Figure 1: High-level overview of the Indian medical device regulatory pathway (Source: Emergo)

With the CDSCO publication of frequently asked questions (FAQs) to accompany the Medical Device Rules 2017, the remainder of this white paper covers the steps in this regulatory pathway and indicates where significant changes were made. We also describe important considerations for those manufacturers whose devices are subject to technical presentation or SEC review requirements, based upon our experience.

Product classification and grouping

Under the Medical Device Rules 2017, there are four primary considerations for manufacturers looking to classify and group their medical devices.

1 Is my product considered a medical device?

As per Medical Device Rules 2017, section 3(zb), “medical device” means:

a. Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i),

b. Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),

c. Devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act.

Additionally, the CDSCO published Gazette Notification S.O. 648(E) to expand the scope of medical device regulation in India to all devices that meet the following definition:

> 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 —
>
> i. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
>
> ii. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
>
> iii. Investigation, replacement or modification or support of the anatomy or of a physiological process;
>
> iv. Supporting or sustaining life;
>
> v. Disinfection of medical devices; and
>
> vi. Control of conception.

Certain device categories are specifically designated by the CDSCO as subject to the medical device regulation in India, including “substances used for in vitro diagnosis,” and additional devices have been periodically added to this list through a process known as “notification.” Thus, medical devices and IVDs subject to registration in India may be referred to as “notified devices.”

2 What class is my medical device?

The First Schedule of the Medical Device Rules 2017 CDSCO has introduced a formal rules-based risk classification system for **medical devices** and **IVDs** based on equivalent classification rules established by the IMDRF. The following table indicates the risk classes introduced by CDSCO:

Risk level	Medical device class	IVD medical device class
Low risk	A	A
Low moderate risk	B	B
Moderate high risk	C	C
High risk	D	D

Although these devices are based on the application of the classification rules established in the First Schedule of the Medical Device Rules 2017, it is important to note that, rather than manufacturers determining the class applicable to their device, CDSCO prescribes the class applicable to specific device types as outlined in **classification list released from time to time**.

3 Is my device subject to exemptions?

The Eighth Schedule of the Medical Device Rules 2017 establishes conditions for exemptions to Chapters of the legislation for certain specific types of devices. The types of devices to which these exemptions apply include:

- Custom-made devices are exempt from all provisions (note: please see the Eighth Schedule for additional details on regulatory requirements around custom made devices)
- Medicated dressings and bandages for first aid are exempt from being covered by a sales license if their manufacturers are licensed
- Devices supplied by registered medical practitioners to individual patients
- Devices supplied by a hospital or dispensary maintained or supported by government or local body
- Mechanical contraceptives are exempt from being covered by a sales license if they are sold, supplied or dispensed within their labelled shelf-life and compliant with product label claims
- Devices imported in small quantities and donated to a charitable hospital for free patient treatment

4 How can my device be grouped?

The Medical Device Rules 2017 established that guidance may be issued by CDSCO governing the grouping of medical devices. Such guidance was published in **March 2018** and establishes criteria for devices to be grouped as:

- Single
- Family
- IVD cluster
- Group
- IVD test kit
- System

Authorized agent designation

Foreign manufacturers wishing to market their devices in India continue to require an in-country authorized agent to manage device registration, importation and distribution in the country. However, the Medical Device Rules 2017 expanded the responsibilities of the agent. As was necessary under the former requirements, the authorization granted by a manufacturer to its agent must be documented by a power of attorney.

Authorized agents must obtain a wholesale license for sale or distribution of medical devices and IVDs. They must further authenticate and register their organization through the online SUGAM portal, after which they will have access to **submit import license/device registration applications**. Foreign manufacturers may now maintain multiple agents — each with their own registration of the same device.

Additionally, import licensing has also been included with the role of the Indian agent under the new rules and is no longer treated as a separate activity. Therefore, foreign manufacturers cannot maintain an independent agent separate from their importer — i.e., only the authorized agent is approved to import products using the registration granted in its name.

Determination of applicability of specific regulatory requirements

One of the most significant changes in the Medical Device Rules 2017 is the establishment of quality management system requirements for medical devices and IVDs under the Fifth Schedule. These requirements are aligned with those of ISO 13485:2003. However, unlike other jurisdictions, the CDSCO has prescribed environmental requirements for medical devices and IVDs to the extent that ISO classification (at rest) requirements for clean rooms have been established for activities related to specific device types. For example, the primary packaging and crimping of cardiac/drug eluting stents must be performed in an ISO Class 5 (at rest) clean room. It is strongly recommended that manufacturers verify compliance with the established QMS requirements, particularly those related to environmental controls.

Based on the feedback from the Drug Controller General of India (DCGI) caveated that these quality system and environmental requirements only apply to Indian manufacturers; however, no formal update or notification has been issued by the regulator with this clarification.

Upon receipt of an application, the Central Licensing Authority may determine that inspection of an overseas manufacturing site is necessary.

This inspection can be performed by the authority or other body for whom this power has been delegated (e.g., Notified Body). If the Central Licensing Authority has any reason to believe that a medical device does not conform to quality standards, or noncompliance with the provisions of the Fifth Schedule, the authority may also direct a team of officers to inspect the manufacturing site. All inspections are also subject to fee payment, including for international inspections.

Free Sale Certificates from GHTF member countries have a higher likelihood of receiving waivers for conducting local clinical trials. The realization of local clinical investigations is mandatory in the following scenarios:

- The device will be imported from a jurisdiction other than Australia, Canada, EU, Japan, or U.S.[1]
- The manufacturer states claim for a new:
  - Intended use
  - Population
  - Material
  - Major design change

Should a local clinical investigation be applicable, it must be performed in accordance with the requirements established under Chapter VII of the Medical Device Rules 2017 and be completed prior to registration.

1. Importers of Class A and B medical devices do not need to undertake a clinical investigation in India, but rather have the option to present published safety and performance data and a Certificate of Free Sale from the country of origin in lieu of undertaking clinical investigation in India.

There are two types of clinical investigations: **pilot clinical investigations** and **pivotal clinical investigations**. For investigational medical devices developed in India, both types of clinical investigations must be carried out in the country. For investigational medical devices developed and studied outside of India, pilot clinical investigations need not be undertaken in India provided the relevant clinical study data is submitted to the Central Licensing Authority.

Upon review of the data, the Central Licensing Authority may request a pivotal clinical investigation or that a pilot study be repeated in India. A pivotal clinical investigation conducted in India is required for all investigational medical devices, except Class A medical devices.

In relation to IVDs, performance evaluation report by the manufacturer needs to be submitted by the applicant for Class B, C and D that is issued by central medical devices testing laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories or by any hospital accredited by National Accreditation Board for Hospitals and Healthcare Providers or by any Central Government or State Government Laboratory of any hospital or of any institute.

A guidance document listing the approved labs/testing centers that need to be considered for conducting performance evaluation has been issued by CDSCO.

Dossier compilation and submission

The dossier requirements for registration include a plant master file, device master file, and regulatory documents consisting of:

- Power of attorney authorized by a manufacturer or its agent
- Certificate of Free Sale (CFS) from a founding member of the GHTF (Australia, Canada, Japan, EU, and/or the U.S.)
- Quality management system certificate and full quality assurance certificate
- Copy of the latest inspection or audit report performed by a Notified Body, national regulatory authority or other competent authority within the last three years
- Performance evaluation reports (for IVDs)

The device master file includes complete information about the medical device, whereas the plant master file includes the information related to the manufacturing site. The device predicate comparison table is a key component of the device master file. The application should be submitted through CDSCO's online SUGAM licensing portal.

The CDSCO processing fee varies from $10-$1,500 (USD) per device depending on risk class, and from $1,000-$3,000 (USD) for manufacturing sites.

Technical presentation (if applicable)

The Central Licensing Authority may request a technical presentation as part of the registration process. The technical presentation lasts no longer than 30 minutes, including discussion and questions, if any. Such presentations are typically requested should the reviewer need some clarification on the information submitted. The reviewer may request further explanation on the device's intended use, indication for use, description, components, etc. The manufacturer and any technical expert that can represent the manufacturer need to deliver the presentation in person at CDSCO's office.

In our experience at Emergo, technical presentations are required for more than 25% of all applications. Therefore, the manufacturer should plan for the necessity of a technical presentation. If the Central Licensing Authority requires a technical presentation, a manufacturer should add approximately three to six months to its registration timeframe. This timeframe also depends highly upon the availability of experts as well as the number of presentations in the authority's queue.

Note: The technical expert should have thorough knowledge of the medical device to deliver the technical information of the device, predicate device, design, etc.

SEC review (if applicable)

A subject expert committee (SEC) review is an additional meeting with technical experts and/or surgeons in the specific field relevant to the medical device in question. The Indian Government's Ministry of Health and Family Welfare has approved 25 panels of experts in various therapeutic areas for evaluation of clinical trial, novel drug, and novel device application categories.

Generally, SEC meetings are necessary for devices where there is no predicate approved in India (i.e., novel devices).

The Central Licensing Authority may refer an application for SEC review if it believes the device in question has no predicate approved in India regarding intended use, material of construction/composition, design, concentration of material, etc. The SEC will decide whether the manufacturer must perform a clinical investigation of the device in India, or if the device can be approved with issuance of a conditional certificate (where the manufacturer must report back periodically on post-market data for a defined timeframe) or can be waived based on available global clinical data.

Note: The SEC review presentation should cover details such as the predicate device, published literature, post-market surveillance data and clinical performance data. If the expert convinces the SEC members that there is sufficient data to demonstrate the device's safety and performance, there is a chance local clinical trials in India will not be necessary.

CDSCO application review and approval

The new rules have outlined official review times for the CDSCO to grant medical device import registrations. The target timeframe has been established as nine months from the date of application, irrespective of whether a device's foreign manufacturing site requires inspection or not.

If an application receives an additional information request (referred to as a "query"), the applicant must submit the response within 45 days. Otherwise, the application will be considered withdrawn and removed from the review queue. If a response cannot be provided within the 45-day period, the applicant may request an extension with valid rationale. Now, medical device registration and import permits have been combined into a single application. Once an application has been approved, companies can immediately begin importing through the authorized agent who submitted the application.

If an application is rejected, the authorized agent can file an appeal with the central government within 45 days.

Post-market requirements

Post-market requirements established in the Medical Device Rules, 2017 include:

1 Registration retention

The registration of medical devices in India is manufacturing site-specific. All devices manufactured at a single facility are issued under a single license number.

Registrations do not expire. However, a maintenance fee is due every five (5) years along with minimum documents unless the registration has been cancelled or suspended. The retention fee varies between $10-$1,500 (USD) per device and $1,000-$3,000 (USD) per manufacturing site.

2 Vigilance reporting

The definitions for recall and serious adverse events are included under Section 3, Chapter I of the Medical Device Rules 2017.

The new rules require manufacturers and importers to immediately initiate a recall when there is reason to believe that a medical device is likely to pose risk to the health of a user or patient during its use. The manufacturer (or for foreign manufacturers, their India Authorized Agent) should immediately initiate procedures for withdrawal of the medical device from the market and inform authorities. This differs significantly from the Drugs and Cosmetics Act, which does not obligate the manufacturer or importer to recall medical devices upon knowledge of risk to users or patients.

Adverse events must be reported whether they occurred in India or elsewhere; this should include any action taken by the manufacturer and/or the applicable national regulatory authority. The India Authorized Agent should file the report with the Central Licensing Authority within 15 days of any administrative action taken, such as market withdrawal (recall), regulatory restrictions, cancellation of market authorization, and/or market notification (i.e., declaration to the public made by the national regulatory authority) and to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Center (NCC).

The Medical Device Rules 2017 also establishes requirements for vigilance reporting during clinical investigations in India. The sponsor of the clinical investigation should report any unexpected serious adverse event that occurred to the Central Licensing Authority within 14 calendar days of knowledge of the occurrence.

3 Change notification

Many types of changes require notification from or approval from CDSCO. The Medical Device Rules 2017 classifies changes as either Major or Minor. Depending on the type of change, pre-approval may be required before the change is implemented (in case of major changes) and simply a notification (in case of minor changes). CDSCO does not currently specify a fee for change notifications. Types of changes and their categorization are specified under the Sixth Schedule as:

Major change

1. Change in material of construction
2. Change in design that shall affect quality in respect of its specifications, indication for use, performance, and stability of the medical device
3. Change in intended or indication for use
4. Change in method of sterilization
5. Change in approved shelf life
6. Change in name or address of manufacturing site
7. Change in name or address of authorized agent
8. Change in label excluding font size, type, color, label design
9. Change in primary packaging material

Minor change

1. Change in design that shall not affect quality in respect of its specifications, indication for use, performance, and stability or the medical device
2. Change in the manufacturing process, equipment, or testing that shall not affect the quality of the device
3. Packaging specifications excluding primary packaging material

Conclusion

The medical device regulatory system in India remains very much under development. According to the Medical Device Rules 2017, regulators issued a list of laboratories for the evaluation of IVD kits. Regulators also issued periodic device lists, which include classification categories (for example, ophthalmology, nephrology and renal care, general hospital, etc.) Stakeholders need to consider the appropriate category classification list to determine the classification level of their devices.

The National Single Window System (NSWS) Portal was established by the Central Government to build a genuine NSWS, which can act as a one-stop shop for all the approvals/licenses/registrations/clearances, as applicable. As of February 2024, only three applications/activities have been developed: Form MD-01 (application for a grant of registration of a Notified Body), Form MD-12, and Form MD-16 (application for a license to manufacture/import for the purpose of clinical investigation, test, evaluation, examination, demonstration or training respectively). All the remaining applications may soon be developed under this portal.

The CDSCO continues to publish regular guidance documents on how to interpret and implement the Medical Device Rules 2017.

Learn more

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- Technical File compilation and review
- Device classification and grouping
- ISO 13485 implementation and gap audits

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About the author

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