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A Comparative Study of Medical Device Regulatory Frameworks: India vs. the European Union

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Abstract

The regulatory frameworks governing medical devices have become increasingly complex and crucial for ensuring patient safety and product efficacy due to rapid technical advancement and expanding international trade. This study examines the medical device regulatory frameworks of the European Union (EU) and India, focusing on device classification, approval processes, clinical evaluation, and post-market surveillance requirements. India controls medical devices under the Medical Devices Rules (IMDR), 2017 and later amendments, whereas the EU operates under the Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostic Regulation (IVDR) 2017/746.Both regions employ risk-based classification systems, according to the report, but the EU framework—which is supported by CE marking, notified authorities, and centralized databases like EUDAMED—shows a more advanced, standardized, and globally recognized regulatory structure. On the other hand, India has achieved significant progress because of digital platforms like SUGAM and centralized regulatory oversight by CDSCO; yet, problems with post-market surveillance transparency and data accessibility persist. The study concludes that while India's regulatory ecosystem is steadily strengthening, greater regulatory alignment with international standards and convergence with the EU could improve patient safety, promote innovation, and facilitate the entry of medical devices into international markets.

Conclusion: The review also explains a brief about India and EU regulatory requirement for registration of medical device and comparative data between two countries.

Keywords: Medical Device, EU MDR, CDSCO, MDR 2017

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1. Introduction

Medical devices are referred to tools, machines, implants, or other similar products used in diagnosing treatment, or diseases prevention and medical conditions in humans. These devices can vary from simple instruments similar to thermometers and tongue depressor to complex technologies such as pacemakers, MRI scanners, and robotic surgery systems. (1) Any instruments, equipment, implement, machine, appliance, implant, in vitro reagent , software, substance, or any comparable or related item that the producer intends to be applied, either separately or in combination, for a medical purpose is considered a medical device, according to the WHO. (2)

The development and regulation of medical device are essential to healthcare systems across the globe. With ongoing technologies innovations and progress in medical science, the regulatory landscape for medical devices has become increasingly intricate. (1) This study aims to provide a broad review of the legislative systems governing medical devices in the EU and India.

In the twenty-first century, India's healthcare system has advanced significantly. It is expected to reach a market worth of $ 280 billion by 2025, having grown at a rate of 10% over the years. (3) India's expenditure was $75 in 2016 for healthcare, significantly lower than that of other regions. In comparison, the united states spent $9,403, the European union (EU) $3,613, China $420, and the worldwide average stood at $1,061. (4)

In India, around 70% of medical gadgets are sourced through imports. (5) There is a big chance for medical device manufacturers to close the gap between imports and manufacturing by producing and selling their products domestically. But creating medical devices is still a very difficult and time-consuming process. (4)

The medical devices approval procedure in India is highly structured, strictly controlled, and overseen by the Indian Medical Device Rules (IMDR), 2017 (6) , and the Medical Device (Amendment) Rules,2020. (7) These regulations cover a wide range of medical device-related topics, such

as categorization, registration, production, importation, labeling, distribution, and post market requirements.

The recently implemented Medical Device Regulation (MDR) in the EU. (8) It places greater responsibility than ever the European Commission, responsible authorities, and notified bodies for ensuring the security of medical equipment.

Clinical evaluation is the first step in providing and validating medical device safety in the European Union. Additionally, it is crucial for the constant evaluation of long-term and the tracking of device performance. In India, clinical evaluation under the IMDR is primarily required during the phase of development of specific medical devices. Although post market specifications do exist, they come with certain limitations. (4) Since both regulatory frameworks were updated and become effective and continue to evolve this article presents a comparison between them.

2. Device Classification

According to the IMDR, classification is determined based on the devices intended use, the level of risk it poses, and other relevant criteria. (6) The central licensing authority (CLA) of India categorizes Medical Devices and IVDMs into four different risk classes and they are shown in Table:1.

Table 1. Classification of medical Device (6)

Class	Level of risk
Class A	Low
Class B	Low-Moderate
Class C	Moderate- High
Class D	High

The following guidelines are used to classify medical devices, or IVDMDs:

- The device's classification is determined by its intended use, or IVDMD.
- Combination devices and accessories are classified separately.
- Software belongs to the same category as the device it is connected to.
- Devices and multiple specified uses are classified according to their highest risk application.
- When multiple classification rules apply, the strictest rule that results in the highest classification is used (4).

The most recent medical device regulation (EU) 2017/745 and In Vitro Diagnostic Regulation (EU) 2017/746 entered into force on 25 may 2017. (9) They replace the three existing directive, taking effect from May 2020 for medical devices and from mid-2022 for in-vitro diagnostic devices. This transition period was granted to manufacturers so they could adhere to the new MD/IVD requirements (Table 2). All medical devices shall continue to adhere to the fundamental standards outlined in the directives until notified bodies are designated to certify under the recently implemented regulations. (10,11)

Table 2. Medical device classification as per EU (12)

Class	Risk Level
I (Non-Sterile)	Low Risk
I (Sterile)	Low/Medium Risk
IIa	Medium Risk
IIb	Medium/High Risk
III	High Risk

3. Regulatory approval process

3.1 European Union

In European, the regulatory approval of medical devices is overseen by European Union (EU) regulations and directives. The Medical Device Regulation (MDR) 2017/745 and the In Vitro Diagnostic Regulation (IVDR) 2017/746, which superseded the earlier directives (MDD & IVDD), make up the primary framework.

Medical devices are categorized based on the degree of risk they pose, duration of contact with the body, and the body part they interact with. This classification determines the applicable regulatory pathways:

Appoint an Authorized Representative: Non-EU manufacturer are required to designate an authorized representative (AR) within the EU, who will serve as the representative with regulatory authorities.

Quality Management System (QMS): Implement a QMS in compliance with ISO 13485, which is mandatory for all device classes. The system should encompass all stages of the product lifecycle, from design and manufacturing to after-market monitoring. (13)

The involvement of a notified authority is required depending on the classification of the device. If a notified body is not required (as is often the case for non-critical devices), some manufacturers may mistakenly assume that no formal "approval" is needed. However, the majority of regulatory requirements still apply regardless of the device's risk classification. For instance: (14)

- Documented proof within the technical file providing adherence to general performance and safety standards.
- A clinical evaluation providing evidence of a favorable benefit-risk ratio.
- Implementation of a post-market surveillance system.
- Creation by the manufacturer of an extensive quality control system.
- Registration of both the gadget and the maker in the EUDMED database (14)

3.2 India

The process of certifying medical devices is expedited by the Central Drugs Standard Control Organization (CDSCO), a division of the Government of India's Ministry of Health and Family(16). Applications for license are submitted via SUGAM, an online licensing

platform. Class A and B medical device manufacturing authorization will be supervised by the SLA, whereas class C and D license approval will be directed to the CLA. (17)

Quality assessment report (QAR) is necessary for class B, C, and D devices at the time of applying for a manufacturing license. Regarding class A medical equipment, however, the QAR must be submitted in less than 120 days of the manufacturing license being granted. (18)

To obtain an Import license, a manufacturing or distribution license is required as a prerequisite. Foreign manufacturers must appoint an authorized Indian representative to hold the license, manage post-market surveillance (PMS) activities, and handle the distribution of medical devices. Applications for import license for all classes of medical devices must be submitted to the central licensing authority. (18)

The criteria for an approval certificate to recognize a global manufacturer, its location, and its products were eliminated by the 2017 regulations. To import and sell goods in India, two separate applications are currently needed: One for registration and another for an import license. (17)

Table 3. Timeframe for obtaining a medical device manufacture or import license (17)

Timeline	Class A	Class B	Class C	Class D
Manufacturing license	45 days	140 days	150 days	150 days
Import License	Within 9 months			

4. Comparative study of key terms and procedure used in EU and Indian device development and licensing processes

Table 4. Terminology comparison between EU and India

Country-specific Processes and guidelines	India medical device rule	European medical device regulations
Definition	In vitro diagnostic drugs, surgical equipment, blood and blood component collecting bags, mechanical contraceptive, pesticides, disinfectants, and other devices that have been legally registered.	Any device, apparatus, appliance, software, implant, reagent, material, or other item that the manufacturer intends to be used either alone or in conjunction with other devices to help people manage disease to help people manage disease, trauma, or impairment; to alter or replace anatomical structures; or to provide information through in-vitro examination without depending on pharmacological, immunological, or metabolic means.
Classification of device	Class A, B, C and D	Class I, IIa, IIb, and III
Clinical evaluation	The validation of the medical device covered both its design and creation stages. Importation and/or manufacturing of the medical equipment requirement, with limited exceptions for certain countries.	An analysis of the device's clinical safety and performance is conducted, and all activities related to the medical device are carried out consistently throughout its entire lifecycle.
Procedure for registering a device	Online registration with the CLA was voluntary until October 2021. Applicants must upload the device details, the ISO 13485 compliance certificate, and the organization's registration number.	Basic UDI-DI (used for device transparency), a safety and clinical performance summary, and CE designation
Similar device	Predicate gadget	Comparable or similar device
Essential requirements	Essential Principles	General security and performance standards
Publicly accessible database focused on safety information	There is no centralized database for reporting adverse events, and safety-related database are not publicly accessible.	EUDAMED is the European union's (EU) central database for medical device. Starting in 2022, it will be accessible to the general public.
Data obtained from post-market clinical trials	Elements such as post-release clinical follow-up reports and periodic safety update reports (PSUR).	Different ways: PMCF, CER, PMSR, PSUR, PMS, post-marketing clinical investigation, and clinical evaluation assessment report.

Table 5. Comparative analysis

Key aspects	EU	India
Regulatory Framework	EU's regulatory framework is more mature, harmonized and globally accepted with the implementation of MDR 2017/745 and IVDR 2017/746.	India's system, governed by the IMDR 2017 and its amendments has seen substantial progress.
Device Classification	Classify on the base of risk from I-III	In India classification is from class A-D and its also based on risk.
Approval process	Here involvement of Notifies Body and the requirements for CE marking create a standardized process.	In India the process is more centralized with CLA and SLA managing approvals.
Clinical evaluation and Post-market Surveillance	The EU mandates ongoing clinical evaluation and PMCF, supported by tools like EUDAMED.	India has started strengthening its clinical evaluation and PMS mechanisms but still lack a centralized public database.

5. Conclusion

The EU's regulatory framework is more mature, harmonized, and globally accepted, especially with the implementation of MDR 2017/745 and IVDR 2017/746. Both the regions use a risk-based classification system. While doing a overall comparative analysis it shows that both India and the EU are committed to improving the regulation of medical devices, the EU's framework is more robust, transparent, and aligned with international standards. India is making significant strides, particularly through the IMDR and online licensing systems like SUGAM, but there is room for improvement in post-market surveillance, centralized data transparency, and harmonized with global norms.

As medical technologies evolve and global trade increases, regulatory convergence, capacity building, and mutual recognition between regions like India and the EU will be essential. In additional to improving patient safety, strengthening these elements will accelerate the development of life-saving medical technology.

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Conflict of Interest

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