

Medical Device Regulations: A Comparative Study of India with European Union

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Abstract

The term “medical device” (MD) encompasses a diverse array of products, such as examination gloves and computerized dermoscopy devices, among others. These devices are subject to regulation inside the European Union (EU) under a recently enacted regulatory framework. The importance of medical devices is experiencing a growing trend in the healthcare sector. One of the main obstacles encountered by companies involved in the development and manufacturing of medical devices is the need to remain updated on regulatory obligations and successfully integrate them into their operational protocols. The authors of this study categorize medical devices according to the regulatory frameworks in Europe and India. The researchers also investigate the regulatory framework pertaining to the regulation of medical devices. In order to analyze the areas in which the Indian legal system falls short in comparison to the European Union (EU), a comparative analysis was conducted in the last section.

Keywords: Medical device, Device classification, Risk, Vitro Diagnostic Devices, Rules & Regulations.

1. Introduction

Medical Devices are designed to improve the health of an individual. Without medical devices, common medical procedures from bandaging a sprained ankle, to diagnosing HIV/AIDS, implanting an artificial hip or any surgical intervention would not be possible.

The progression of medical device technology has the potential to empower patients in actively managing their own health. An illustration of such a device is the portable, battery-powered apparatus that individuals diagnosed with diabetes can employ to monitor their blood glucose levels. By engaging in self-monitoring, individuals with diabetes are able to ascertain their blood glucose levels and make necessary adjustments to their dietary intake, insulin administration, or physical activity in order to properly manage their condition. Numerous additional instances of diagnostic equipment, such as stethoscopes and X-ray machines, facilitate enhanced auditory and visual perception for clinicians. Rehabilitative equipment, such as dental prosthesis and artificial limbs, serve to restore impaired functions and enhance overall quality of life. Life-sustaining apparatus, such as cardiopulmonary bypass machines and respiratory support systems, execute essential tasks for individuals with impaired health. The quantity of medical gadgets in circulation is substantial. These gadgets not only enhance patient outcomes but also guarantee their safety and comfort throughout medical procedures.

In May 2007(*WHO EMRO | Resolutions | Strategy | Health and Biomedical Devices*, 2007), the inaugural resolution concerning health technologies was officially endorsed by the World Health Organization’s (WHO) World Health Assembly (WHA) with the designation WHA 60.29. This resolution established a comprehensive framework that placed significant emphasis on health technology, with a particular emphasis on medical devices. From 2007 to 2021, there was a significant growth in the global revenue generated by the medical technology business. Based on the available data, it can be observed that the sales of medical technologies yielded a revenue of 295 billion euros in 2007, which subsequently increased to 536 billion euros by 2021. The projected growth of revenue derived from medical technologies indicates a continued upward trend, with an estimated value of 633 billion euros anticipated to be achieved by the year 2024. Medical technology encompasses a broad range of instruments and apparatuses utilized in the field of medicine, as well as diagnostic tests conducted outside of the living organism, commonly referred to as in vitro diagnostics.

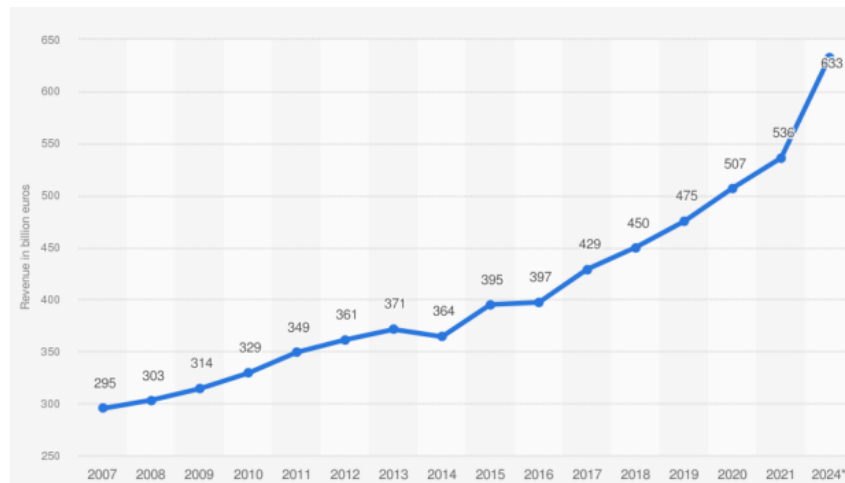


Figure 1 Worldwide revenue of medical technology industry from 2007 to 2021, with a forecast for 2024 (in billion euros) (Revenue of MedTech Industry Worldwide 2021, 2022)

In 2014 (Braniff, 2014), the WHO adopted a resolution regarding regulatory system strengthening for medical products (WHA 67.20). The Resolution states “effective regulatory systems are an essential component of health system strengthening and contribute to better health outcomes”. In the context of Resolution 67.20, the growing interest in medical devices in the global health community and the act of regulatory systems for medical devices in many countries, WHO decided to develop this document. It is intended to provide guidance and support to WHO Member States that have yet to develop and implement regulatory controls relating to medical devices, as well as to jurisdictions that are continuing to improve their regulatory frameworks as they take steps to ensure the quality and safety of medical devices available in their countries. The initial section of this study provides an overview of the historical context surrounding Medical Device Regulation. The subsequent section provides a brief summary of the categorization of medical devices in the European Union and India. The third section of this study examines the similarities and differences between the Indian Medical Devices Rules (IMDR) and the European Union (EU) Medical Device Regulations. Finally, the author provides a final recommendation based on their analysis of the comparative table.

1.1. Historical Overview

As the use of medical devices and medical equipment grew in the 19th and early 20th centuries in hospitals and doctor’s offices, larger volumes of devices were being produced and sold. However, there was a paucity of any control or regulations of medical devices. Most regulations were drug related. It was not until the mid-20th century that several countries started implementing medical device-specific rules and regulations to ensure the safety of the general public. These regulations were completely separate from the drug-related regulations. Before World War I, several countries attempted to establish their individual, regional regulations. Most of these regulations were either included in or buried under drug regulations. Post-World War II, there was a need to establish a separate regulation for medical devices to ensure safety for patients and public health (Brief History of Medical Devices and Regulations, 2021).

The Food and Drug Administration’s (FDA) oversight of food and drugs began in 1906 (*The 1906 Food and Drugs Act and Its Enforcement*, 1906) when President Theodore Roosevelt signed the Pure Food and Drugs Act. Since then, Congress has expanded the FDA’s role in protecting and promoting the development of human and veterinary drugs, biological products, medical devices and radiation-emitting products, human and animal food, and cosmetics (*A History of Medical Device Regulation & Oversight in the United States*, 2023). In this act, it was first discussed about medical devices regulation. In the 1960s and 1970s, Congress responded to the public’s desire for more oversight over medical devices by passing the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (*The Development of the Medical Device Amendments*, 1996). In 1982, the organizational units at the FDA that regulated medical devices and radiation-emitting products merged to form the Center for Devices and Radiological Health (CDRH).

2. Medical Device and its classification

2.1. Definition of Medical Device

According to the European definition, a medical device is “any instrument, apparatus, appliance, material, or other product, whether used alone or in combination, including the software necessary for its correct application intended by the manufacturer to be used for human beings for the purpose of:

- Disease detection, analysis, tracking, and correction or relief,
- Injury or disability assessment, monitoring, treatment, relief, or compensation.
- Analyzing, replacing, or altering an anatomical structure or physiological process.
- Regulating the reproductive process, which relies not on pharmacological, immunological, or metabolic mechanisms to carry out its primary intended activity in or on the human body but which may be aided in its function by such mechanisms”(COUNCIL DIRECTIVE 93/42/EEC, 1993).

Medical devices encompass a wide range of instruments and apparatuses, spanning from basic items such as band aids and contact lenses to more complex equipment including x-ray machines, hip implants, pacemakers, crutches, hospital beds, and in vitro diagnostic gadgets. Medical equipment is commonly categorized into subgroups. In the European context, medical devices are categorized into three distinct classes, namely active implantable medical devices (AIMD), general medical devices, and in vitro diagnostic devices (IVD). These groups are acknowledged and employed by other nations as well. The primary distinction across nations is in the manner in which these devices are governed. Medical devices are subject to regulatory frameworks that vary across different countries. In certain jurisdictions, medical devices are classified and controlled as pharmaceuticals, whereas in other jurisdictions, distinct rules specifically tailored for medical devices are in place. Medical equipment can be subject to regulation either as a collective entity or individually, typically falling into one of the subcategories. In Europe, medical devices are typically categorized into three main groups: noninvasive devices, invasive devices, and active devices. An active medical device refers to a gadget that necessitates an external energy source in order to operate effectively. An intrusive medical device refers to a product that is introduced into the human body in some manner. The device is afterwards referred to as invasive, surgically invasive, or implanted, based on the method of entry into the body and the timing of its introduction. An in vitro diagnostic device refers to a substance, product, apparatus, or system employed for the purpose of analyzing samples derived from human tissues or fluids in order to obtain pertinent information. In the field of medical diagnostics, in vitro diagnostic equipment are further categorized into subgroups(Landvall & Standardisering i Sverige., 2019).

2.2. Classification of Medical Devices

According to the Medical Device Amendments of 1976 (MDA, P.L. 94-295), the Food and Drug Administration (FDA) categorized all medical devices that were available in the market before to the enactment of the amendments, referred to as preamendment devices, into three distinct classes. The definitions for the three classes, namely Class I, Class II, and Class III, were established by Congress in accordance with the level of danger presented to patients by the devices, which are categorized as low-risk, moderate-risk, and high-risk, respectively(*FD&C Act-Section 513*, 1976). Examples of each class are listed in Table 1.

Classification of Devices	Description	Regulations for Security and Efficiency	Required Submission
Class I	supplies for minor surgery (elastic bandages, gloves, scissors)	General Controls	Registration only unless 510(k) specifically required
Class II	surgical drapes, infusion pumps, and powered wheelchairs	General Controls & Special Controls	510(k) notification unless exempt -IDE possible
Class III	implants such as heart valves, breast implants filled with silicone gel, and cerebellar stimulators. metal-on-metal hip joint, certain dental implants	Premarket Approval & Quality Assurance General Controls	PMA submission - IDE likely 510(k) notification

Table 1 Medical Devices Classification(Darrow et al., 2021)

The classification of a device dictates the specific regulatory obligations that a maker is obligated to adhere to. The next section provides a more comprehensive description of the regulatory requirements for each class. All three categories of medical devices regulated by the FDA are subject to general controls, unless specifically exempted by regulatory provisions. These general controls are the sole level of controls applicable to Class I devices (*Regulatory Controls*, 2014). General controls encompass a range of regulatory measures, such as establishment registration, device listing, premarket notice, and adherence to good manufacturing practice regulations.

Class I devices are medical devices that are regulated under existing legislation. These devices are considered to have broad controls in place, which are deemed adequate to provide a reasonable level of safety and effectiveness (Pilot, 2012). Several Class I devices are not subject to premarket notice and/or Quality System (QS) regulation requirements, but they must nevertheless adhere to the remaining general regulations (*ECFR :: 21 CFR Part 862*, 2014). An exemption is granted to a device when the FDA determines that it has a minimal risk of causing illness or injury to patients (*ECFR :: 21 CFR Part 862*, 2014).

Class II devices are categorized as such according to current legislation, as they do not meet the criteria for classification as class I devices due to the fact that general controls alone are deemed inadequate in ensuring the device's safety and effectiveness (*Federal Food, Drug, and Cosmetic Act (FD&C Act)*, 2018). Class II encompasses medical devices that present a moderate level of risk to patients. This category may encompass novel technologies for which specific information or special measures have been established to minimize or alleviate potential risks (*Regulatory Controls*, 2014). Special controls typically pertain to specialized devices and encompass various measures such as specific labeling requirements, obligatory performance standards, and post-market surveillance. At now, it is observed that a proportion of 15% of device types categorized under Class II are subjected to the implementation of specific restrictions ("Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years," 2011). While the majority of Class II devices necessitate premarket notification through the 510(k) process, there exist a limited number of exemptions as per regulatory guidelines (*Overview of Device Regulation*, 2020).

Class III devices are those that do not meet the criteria for classification as a Class I device due to insufficient information regarding the adequacy of general controls in ensuring the device's safety and effectiveness. Additionally, they do not meet the criteria for classification as a Class II device due to insufficient information regarding the effectiveness of special controls in ensuring the device's safety and effectiveness. These devices are either intended for use in supporting or sustaining human life or are of significant importance in preventing impairment of human health. Furthermore, they pose a potential unreasonable risk of illness or injury and therefore require premarket approval to provide reasonable assurance of their safety and effectiveness (*Device Classification Under Section 513(f)(2)(De Novo)*, 2012).

In alternative terms, it might be argued that both general and specific controls alone are inadequate in ensuring the safe and effective utilization of a Class III device. Class III encompasses medical devices that serve the critical functions of supporting or sustaining life, as well as devices that pose a significant or potentially unjustifiable risk of causing illness or injury to patients. Unless the maker submits a request or petition for reclassification, devices that do not fall within Class I or II are automatically categorized as Class III (*Device Classification Under Section 513(f)(2)(De Novo)*, 2012).

During the drafting of the Medical Device Amendments (MDA) of 1976, it was observed that there were a limited number of medical devices that were designed for permanent implantation or intended to provide life-sustaining functions. The 510(k) method was primarily designed for medical equipment that require a lower level of scientific scrutiny, such as surgical gloves and hearing aids (Zuckerman et al., 2011). Over the course of time, the 510(k)-review process of the FDA has encountered challenges due to the increasing complexity and significant changes observed in new devices (Zuckerman et al., 2011).

In the latter part of 2009, the Food and Drug Administration (FDA) initiated the 515 Program Initiative with the aim of expediting measures pertaining to the outstanding Class III device categories (*515 Project Status*, 2009). Several Class III devices that were subject to regulation through the 510(k) program include the metal-on-metal hip implant, specific dental implants, automated external defibrillator, electroconvulsive therapy device, pedicle screw spinal system, intra-aortic balloon and control system, as well as various device types associated with pacemakers (*515 Project Status*, 2009). The process for reclassifying a device was altered from regulation to an administrative order with the implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012 (*Food and Drug Administration Safety and Innovation Act (FDASIA)*, 2012 s.608(b)). Since 2013, the Food and Drug Administration (FDA) has issued several final orders in the Federal Register to reclassify numerous Class III device types that have not yet been reclassified (*515 Project Status*, 2009).

2.2.1. Classification according to Indian System:

In accordance with the device’s intended application, the risks connected with the device, and other factors included in the IMDR(Welfare, 2017), the Central Licensing Authority (CLA) categorizes Medical Devices and In Vitro Diagnostic Medical Devices (IVDMDs) into four risk classes, namely A, B, C, and D. This classification is determined by the application of a predefined set of classification principles (2). Additionally, the CLA specifies distinct conformity assessment procedures that are applicable to each respective category of devices (Figure 2).

The categorization criteria for medical devices, excluding in vitro diagnostic devices (IVDs), are contingent upon the characteristics exhibited by the device, including factors such as:

- delivers medicinal products, energy or radiation;
- incorporates human or animal tissues or cells;
- is used in combination with another medical device
- could modify blood or other body fluids;
- is invasive and if so, to what extent and for how long;
- incorporates medicinal products.
- is an active medical device.
- is life supporting or sustaining

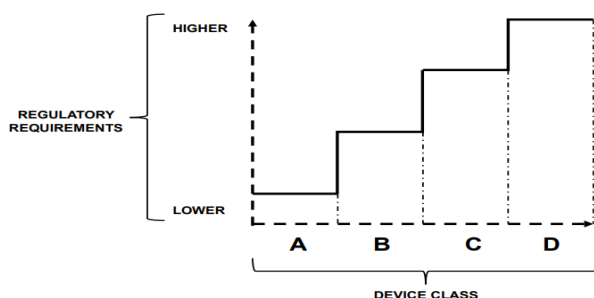


Figure 2 Impact of device classification on regulatory scrutiny

Class	Risk	Examples
A	Low	Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, IVD instruments, <u>microbiological culture media</u>
B	Low-moderate	Surgical gloves, infusion sets, pregnancy tests
C	Moderate-high	Condoms (unless with spermicide (class D)), infusion pumps, neonatal incubators, therapeutic and diagnostic X-ray, lung ventilators, haemodialysers, anaesthesia equipment, self-test glucose strips, IVDs for the diagnosis of Neisseria gonorrhoea
D	High	Implantable cardioverter defibrillators, pacemakers, breast implants, angioplasty balloon catheters, spinal needle, IVDs for the diagnosis of HIV, hepatitis C or hepatitis B

Table 2 Examples of medical devices by risk class

2.2.2. Classification in European Union

The European Union (EU) utilizes a four-tiered classification system depending on the potential for harm, the duration of use, and the level of intrusiveness of a device’s contact with a human body(Commission regulation, 2006). The risks associated with using class I medical devices and the vast majority of in vitro diagnostic (IVD) medical devices are minimal(*COUNCIL DIRECTIVE 93/42/EEC*, 1993). Device manufacturers can self-certify that their products meet marketing criteria without involving a notified body (NB), but they must keep a set of required technical documents available for review. Class IIa medical devices cannot be sold without first being verified for conformity by a Notified Body (NB)(*DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in Vitro Diagnostic Medical Devices*, 1998 art. 9). Class III medical devices, active implantable medical devices, and some in vitro diagnostic (IVD) medical devices all require NB design dossier approval prior to commercial release(*DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in Vitro Diagnostic Medical Devices*, 1998 art. 9). In contrast to the U.S. third-party system, in which the FDA evaluates the third-party report and ultimately decides whether or not the device can go to market, in the EU, no government entity reviews the finding of the NB that the product complies with the applicable EU directive.

EU Member States, like their American counterparts, can limit the distribution of goods that don’t meet the standards set forth in EU directives. If a device is released to the market based on an NB’s judgment of compliance but is later determined to not be compliant with regulations of an EU Member State following the EU directive, the limitation may apply. A Member State’s ban on a product due to unjustified risks to human health or property is subject to scrutiny by the European Commission and, if necessary, the European Court of Justice(*DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Safeguard Clause- Article 8*, 1998). The United States legal system employs a procedure quite similar to this for all technological gadgets(Food et al., 1988).

3. Regulation of Medical Devices in the European Union and India

3.1. Role of EU in regulating medical devices

The EU Medical Device Regulation is a new piece of legislation that will replace the MDD and apply to all medical devices sold in the European Union(*Difference Between A Regulation And Directive (European Law)*, 2020) (with an expanded definition that includes products not previously considered medical devices). Although the MDR became law on May 26, 2017, the majority of its regulations governing the approval of medical devices will not become effective until May 26, 2020(*Europe-Key Dates and Roadmap for Implementation of New Rules on Medical Devices* , 2017).

The primary objective of the European Union Medical Device Regulation (EU MDR) is to modernize and enhance the regulatory structure governing the medical device industry inside the European Union, as outlined in table 3. Moreover, the Medical Device Regulation (MDR) was formulated with the aim of enhancing market transparency, ensuring regulatory certainty, and establishing a standardized regulatory procedure(Rose, 2017).Both European Union authorities and market participants have expressed concerns regarding the lack of consistency in the current regulatory framework among member states of the EU. The presence of this mismatch has given rise to accusations of engaging in regulatory arbitrage within the medical devices industry(Horowitz et al., 2018) (i.e., the deliberate registration of devices in EU countries with weaker enforcement of regulatory procedures).

Major Regulatory Stage	Change from MDD to MDR
Replace MDD with MDR	This initiative aims to enhance the rigorous nature of current research and clinical trial protocols, hence raising the threshold for the inclusion of specific research findings in the assessment of safety and efficacy for medical devices. In light of recent developments, it has been mandated that lower-risk items and a more extensive range of medical devices would hereafter necessitate the implementation of clinical trials.
Conformity assessment procedures	The utilization of unique device identification (UDI) codes is mandated for medical devices, while the requirement for CE certifications is extended to encompass a range of items that were not previously included under the Medical Devices Directive (MDD).

Post-market surveillance	According to the Medical Device Regulation (MDR), companies manufacturing technologically advanced items categorized as class II or III are obligated to perform annual evaluations on the performance of their products in the European Union market. These assessments should also consider any advancements that could potentially affect the efficacy or health outcomes associated with their devices. In order to enhance their operations, these organizations are required to gather additional data and adopt a more transparent approach.
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Table 3 Major changes from the MDD to MDR

Finally, the MDR aims to enhance the regulatory approval and enforcement process. An instance that may be cited is the recall that occurred in 2012, wherein a substantial number of defective breast implants were withdrawn from the market. These implants were manufactured by a French medical device company (Greco, 2015) (the PIP controversy) due to the use of industrial-grade rather than medical-grade silicone spurred significant public health concerns and highlighted a need for a stronger regulatory approval and enforcement process for medical devices.

Several of these advancements influenced significant modifications that took place in European Union (EU) medical device legislation during the transition from the Medical Device Directive (MDD) to the Medical Device Regulation (MDR). New provisions in the Medical Device Regulation (MDR) mandate the compensation of consumers impacted by faulty medical equipment, including in cases where the producer has the financial capacity to fulfill this obligation (Art. 69 Medical Device Regulation - Damage Compensation, 2017). Further, MDR's imposition of mandatory, unannounced audits of medical device firms and NBs (Art. 52 Medical Device Regulation - Conformity Assessment Procedures, 2017) can be directly connected to gaps revealed by the breast implant scandal (European Commission, 2014). Moreover, there has been a notable advancement in the technological sophistication of contemporary medical devices compared to the period when the previous Medical Device Directive (MDD) was implemented in 1993. This progress is evident in the large increase in the amount of data being gathered and communicated by these devices. The awareness of this transformation has played a crucial role in shaping the new data-entry obligations outlined in the Medical Device Regulation (MDR).

The Medical Device Regulation (MDR) has a significant influence on several stages of the approval procedure involved in the introduction of medical devices to the market. This section will elucidate the modifications in relation to key phases of the medical device approval process, encompassing research and clinical trials, as well as conformity assessment. The assessment procedures for CE bodies, post-market surveillance activities, and device recall processes in the European Union Medical Device Regulation and the United States medical device industry are examined.

3.2. Indian scenario for the regulation of Medical Device

The Drug and Cosmetic Act of 1940, passed by the Indian Parliament, serves as a regulatory framework governing the importation, manufacturing, and distribution of pharmaceutical products within India. The primary objective of the Act is to guarantee the safety, efficacy, and compliance with state quality standards of pharmaceuticals and cosmetics being marketed in India. The initial legislation encompasses the regulation and preservation of the standards of cosmetics and pharmaceuticals. It also entails the formation of a panel of technical specialists who can offer guidance to both the national and state governments on topics of a technical nature. This legislation specifically outlines the regulations pertaining to the distribution, manufacturing, importation, and sale of cosmetics and pharmaceuticals. One of the primary shortcomings of this act lies in its narrow focus on the preservation of the quality of cosmetics and medications. The statute in question does not contain any specific provision addressing the laws, regulations, and guidelines pertaining to medical devices, which encompass many concerns and challenges.

The Drugs and Cosmetics Act of 1940 is a legislative measure that was implemented by the Central Legislative Assembly before to India's independence. The ongoing process of reviewing outdated laws and revising existing ones is essential to suit evolving needs and the integration of new technologies. The government has consistently stressed the necessity of reviewing outdated laws and regularly repealing and amending legislation, leading to the introduction of bills in Parliament for this purpose. A committee was established to draft the New Drugs, Cosmetics and Medical Devices Bill, in response to the recommendations of the Central Government and the perceived necessity for comprehensive legislation. In accordance with the suggestions put forth by the Committee. The Ministry of Health and Family Welfare is responsible

for overseeing matters related to public health and the well-being of families. The Indian government has put out a draft bill titled “New Drugs, Medical Devices and Cosmetics Bill, 2022” with the aim of aligning with evolving requirements, contemporary circumstances, and technological advancements. The primary objective of the Bill is to modify and consolidate the legislation pertaining to the importation, production, distribution, and commercialization of drugs, medical devices, and cosmetics. The aim is to guarantee the quality, safety, effectiveness, performance, and clinical testing of new drugs, as well as the clinical examination of investigational medical devices. The Bill also addresses any associated or ancillary matters. Upon careful examination of the law, it becomes evident that the section pertaining to the definition of medical equipment is insufficient in encompassing all emerging technological advancements, such as Internet of Things (IoT) and Artificial Intelligence (AI) based gadgets. Moreover, in the absence of established protocols mandated by regulatory bodies, the introduction of medical devices incorporating cutting-edge technologies such as Artificial Intelligence (AI) and Internet of Things (IoT) into the market lacks a standardized testing procedure. If medical equipment is imported and introduced into the Indian healthcare sector market for use by patients. In the event of malfunctions or adverse incidents resulting from the utilization of medical devices, who would bear the responsibility? The determination of territorial jurisdictions remains unaddressed within the provisions of this measure.

4. The EU’s Medical Devices Regulation and the EU’s in Vitro Diagnostic Regulation are compared and contrasted with India’s Medical Devices Rules (IMDR)

The recently introduced rules by the European Union prioritize the needs and well-being of patients, while also imposing rigorous standards for the performance and safety of medical devices both before to and following their introduction into the market. The medical devices and in vitro diagnostic medical devices (IVDMDs) inside the European Union (EU) are regulated by two distinct guidelines, namely the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR), respectively (*REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*, 2017). The IMDR incorporates various approval procedures, resembling those of the European Union, which require the device to effectively carry out its intended tasks. It encompasses all In Vitro Diagnostic Medical Devices (IVDMDs) and a specific subset of medical devices that are not currently subject to regulation as pharmaceuticals under the pharmaceuticals and Cosmetics Act of 1940 (Ministry of Health and Family Welfare, 1940).

Table 4 presents a comparative analysis of major terminologies and processes involved in the development and approval stages of devices, with a focus on highlighting the similarities and differences between India and the European Union (EU). These references may serve as a point of reference for future modifications in IMDR guidelines and are further elaborated upon in the Way Forward section.

Country Process or terms guidelines	India Medical Devices rules including IVDMDs	Europe Medical device regulations	Europe In vitro diagnostic regulation
Definition (summary)	The drugs utilized for the purpose of in vitro diagnosis, together with the surgical instruments, blood and blood component collection bags (with or without anticoagulant), mechanical contraceptives, disinfectants, insecticides, and other devices that have been appropriately registered.	An instrument, apparatus, appliance, software, implant, reagent, material, or any other article that is designed by the manufacturer to be used, either independently or in conjunction with other items, for the purpose of aiding human beings in the treatment of disease, injury, or disability, as well as for the alteration or substitution of anatomical structures, or for the provision of information through in vitro examination, without the use of pharmacological, immunological, or metabolic methods.	In vitro diagnostic medical devices (IVDMDs) encompass a range of medical devices including reagents, reagent products, calibrators, control materials, kits, instruments, apparatus, pieces of equipment, software, and systems. These devices are specifically designed for use in laboratory settings to examine specimens. The purpose of these examinations is to ascertain the safety and compatibility of potential recipients, forecast treatment responses or reactions, and establish or monitor therapeutic interventions.

Devices Covered	As mentioned before, this pertains to the devices that have not yet been subjected to regulation as pharmaceuticals under the pharmaceuticals and Cosmetics Act of 1940.	As above	As Above
Devices Classification (in increasing order of risk posed)	Class A, B, C and D	Class I, IIa, IIb and III	Class A, B, C and D
Clinical evaluation	The validation process for the medical device encompassed both design and development aspects. The import and/or production of the medical equipment is a mandatory condition, with limited exceptions for specific nations as outlined in the research document.	Analysis on the clinical safety and performance of the device. The activities associated with the medical device are performed consistently during its entire duration.	NA
Performance evaluation	The process of design and development validation was conducted for the In Vitro Diagnostic Medical Device (IVDMD). The importation and/or manufacturing of the In Vitro Diagnostic Medical Devices (IVDMD) necessitates compliance with certain requirements.	NA	analysis of the clinical safety and performance of the device in question. During the entire duration of the In Vitro Dry Matter Digestibility (IVDMD) procedure
Evaluation report	Clinical evaluation report for medical devices, without specifying any specific information, as well as the performance evaluation report for in vitro diagnostic medical devices (IVDMDs).	Clinical evaluation report	Performance evaluation report
Clinical Investigation report	Clinical investigation report and clinical performance evaluation report for in vitro diagnostic medical devices	Clinical investigation report	Performance study report
Devices registration process	Registration online with CLA Voluntary until October 2021 Upload the device's information, ISO 13485 compliance certificate, and the organization's Registration No.	Basic UDIDI, (used for device traceability) Safety and clinical performance summary CE designation and CE mark	NA
Comparator devices	Predicate Device	Equivalent Device	
essential requirements	Essential Principles	General security and performance standards	

public databases devoted to safety information	There is no centralized database for reporting side effects. No public access to safety-related databases	EUDAMED is the European Union's (EU) main database for medical equipment. Beginning in 2022, it will be open to the general public.	
Data from post marketing clinical trials	Aspects such as Clinical follow-up reports after product release PSUR	Different ways: <ul style="list-style-type: none"> • PMSR • PSUR • PMS • Post marketing clinical investigation • PMCF • CER/PER • Clinical evaluation assessment report (prepared by the notified body) 	
The Structural and Temporal Variability of the PSUR	PSUR Frequency Band Structure Proposed (Across All Device Classes) In the first two years, every six months. For the next two years, once per year	There is currently no plan in place for the PSUR frequency. At least once a year, for devices in Classes IIb and III At regular intervals, and at least once every two years for Class IIa equipment. The Class I devices are exempt from the PSUR	
PSUR requirement	For all class of devices	For Class IIa, IIb and Class III devices	For Class C and Class D devices

Table 4 Terminology or processes comparison between India and European Union for medical devices/*In vitro* diagnostic

5. Way Forward

In the past few years, India's healthcare and medical device industries have advanced significantly. With the implementation of Medical Device Rules in 2018, India has forged a new path in the medical device industry. Today, processes are more transparent, and governments are encouraging manufacturers to produce more domestically rather than import. Comparing IMDR(Welfare, 2017) to recent EU regulations MDR(Act, 2020) and IVDR(*REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*, 2017), we see that India has a great deal of room to exploit untapped areas of governance, transparency, and convenience of doing business due to regulatory norms.

The information provided by the IMDR (including amendment 2020) can be confusing or incomplete. For instance, the IMDR more often than not refers to the plan as a clinical performance evaluation plan rather than a clinical investigation plan; mentions the reporting of suspected unexpected serious adverse reactions for clinical investigation but not for clinical performance evaluation; and similarly mentions clinimetric testing for clinical investigation but not for clinical performance evaluation. Furthermore, the EU MDR and IVDR discuss various tools and methods of the PMS system for the manufacturer, including but not limited to post-market surveillance report (required for class I devices), periodic safety update report (required for class IIa, IIb, and III devices), and PMS (includes PMSR and PSUR), whereas IMDR only covers vigilance reporting, post-marketing clinical investigations, and PSUR (required for all device classes).

Comparatively, in IMDR, CE (the equivalent process for IVDMDs is performance evaluation) is required only once prior to marketing the device, while in the EU, Clinical Evaluation and Performance Evaluation are required throughout the lifecycle of the device, i.e., both before and after the marketing of the device. In a similar vein, the European Union (EU) requires clinical safety and efficacy data to be submitted alongside other information before a medical device can be

registered with the CE certificate. There is a lack of regulation for device-related adverse events in India because registration does not necessitate significant pre-marketing clinical safety data.

Despite the enactment of the Indian Medical Devices Regulations (IMDR), many medical devices in India are still classified as drugs under the Pharmaceuticals and Cosmetics Act of 1940. The CDSCO may reorganize these criteria and bring all medical devices under a single umbrella in future updates to the recommendations, thus standardizing the norms and standards for all of these devices. As a result, more medical equipment manufacturers will feel comfortable investing in India, making for an easier business climate overall.

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