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A Leap for Medical Devices Regulation in India and its Comparison with United States and European Union Regulations

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ABSTRACT

The Indian medical devices sector is the sunrise sector and holds the potential to quickly become one of the top countries in the global medical devices market share. In the patient-centric era, this paper aims to comprehensively analyze medical device regulations in India and compare them horizontally with United States U.S. and European Union (EU) regulations. Data from open sources, such as reports, different search engines, etc., were considered for an in-depth analysis of the regulatory landscape in India, the US, and the EU. One of the significant comparative findings indicated that CE (European Conformity) is essential to EU regulation for ensuring medical devices' safety and effectiveness (efficacy). In contrast, notified bodies/central licensing authority (CLA) in India and U.S. Center for Medical Devices and Radiological Health (CDRH) perform the same. Variations in device classification, pre-market approval requirements, post-market surveillance, validity period, and quality management systems were also observed.

Despite significant developments in the medical devices rules (MDR)-2017, various challenges such as specific compliances for software as medical devices (SaMD), futuristic healthcare technologies regulations, and limited designated labs for performance evaluation of In-vitro diagnostics (IVD) medical devices, which needs to be addressed enabling multiple fold increment in the medical device market share. Recommendations include creating a unique quick response (QR) code for each medical device, creating a database of technical information on approved devices, and strengthening materiovigilance. These steps are essential to ensuring the quality and safety of medical devices and enhancing their competitiveness in the global market.

Keywords: Medical Device, Device Classification, Risk Assessment, Quality Management System, Medical Devices Rules.

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1. Introduction

The Global Harmonization Task Force 2012 (GHTF/SG1/N071:2012) defines a "Medical Device" and "*In-Vitro* Diagnostic (IVD) medical device" as follows: “Any instrument, apparatus, equipment, implant, machine, appliance, implant, consumables and disposables, reagents for in vitro use, software, material, or another similar or related article,. intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) as shown in Figure 1, and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but may be assisted in its intended function by such means (Force, 2012).

In recent years, the medical devices industry has experienced exponential growth globally after the emergence of corona virus disease 2019 (COVID-19), and it is still growing quickly. The world has shown a shift in behaviours, work culture, economy, and beyond due to the COVID-19 pandemic. Further, it has significantly raised the importance of manufacturing/importing medical devices or IVD as a key player in the prevention, diagnosis, treatment, monitoring, and management of all medical conditions, diseases, illnesses, interventions, and disabilities (see Figure 2).

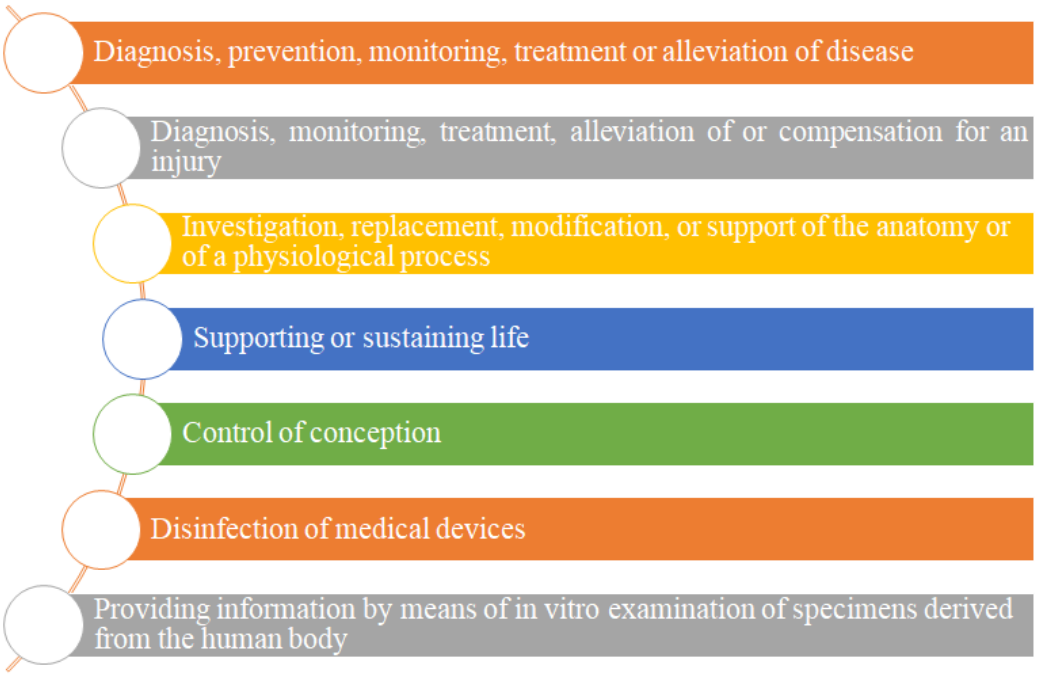

Figure 1. Graphical denotation of medical device and *in-vitro* diagnostic (IVD) medical devicedefinition

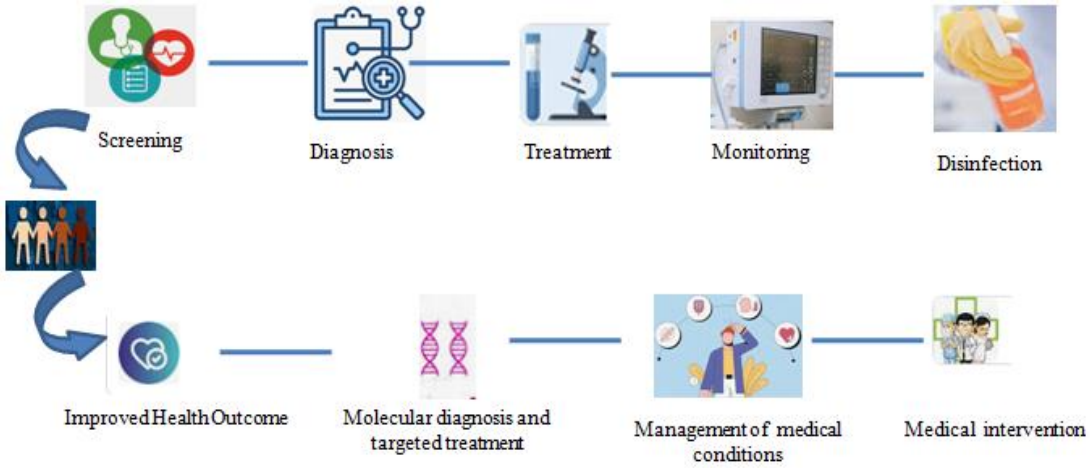

Figure 2. Medical devices as key players towards the goal of universal healthcare

1.1. Indian Medical Device Industry: Statistics Portrayal

The Indian medical devices industry, sharing the global medical device market of 1.65%, is a sunrise sector of $11 billion, growing steadily at a compound annual growth rate (CAGR) of 15% over the last 3 years (2020-2023). However, current medical market equipment is expected to record a 12.6 % CAGR from 2024 to 2033 (Customs market insights; India Medical Equipment Market 2024–2033, 2024). 2024, it is projected to reach $ 6 billion; by 2033, the valuation is anticipated to reach $17 billion (see Figure 3).

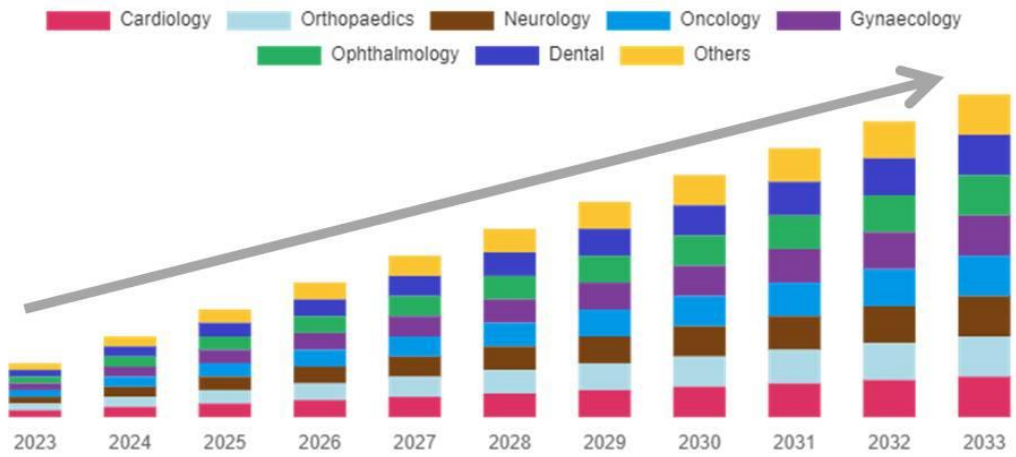

Figure 3. Indian Medical Equipment Market-current projection 2024-2033 by application (source: customs market insights India Medical Equipment Market 2024–2033 (*Customs market insights; India Medical Equipment Market 2024–2033*, 2024)

India is Asia's fourth largest medical device market, following Japan, China, and South Korea. It is among the top 20 global medical device markets (*Indian Medical Device Market, Annual Report* – 2022-2023). However, the sector faces a substantially high import dependency of 75-80% (see Figure 4). Moreover, India hosts approximately 750-800 domestic medical device manufacturers, which meet nearly 65% of the domestic market in disposable and consumable segments (*Boosting the Indian Medical Device Industry* 2023; *Note on Health and Pharmaceutical Sector. Invest India*, 2024).

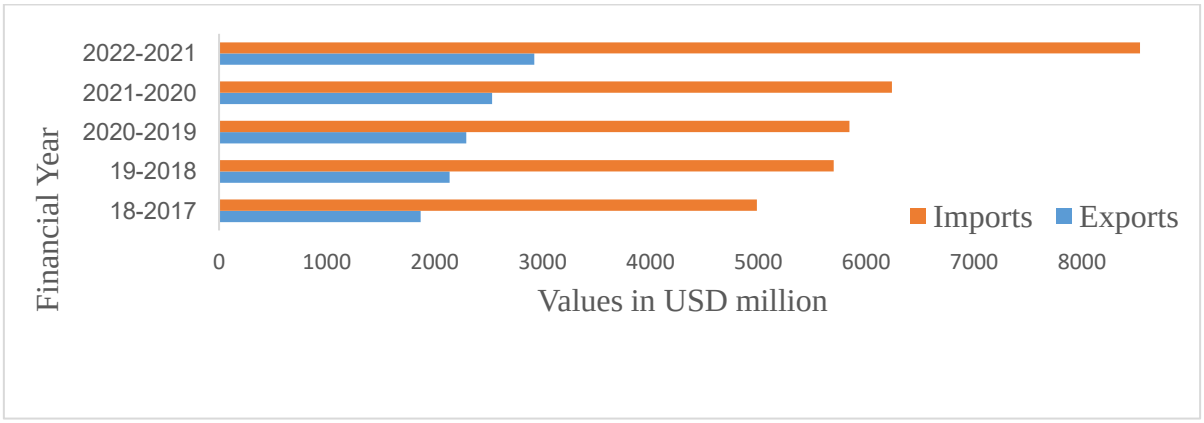

Figure 4. Exports and Import of Medical Devices in India (Source: Engineering Export Promotion Council of India-EEPC, India *(Final Report, Survey of Medical Devices Clusters*, 2023)

In particular, India remains immensely dependent on imports despite the significant presence of Indigenous manufacturing for higher-end medical diagnostics and testing products such as consumables and disposables, surgical instruments, implants, electronic equipment, and IVD reagents from the U.S., Germany, China, Singapore, and the Netherlands, which are the top

exporters of such devices to the country (*Final Report, Survey of Medical Devices Clusters,*, 2023; *India imports 80% of its requirement of medical devices: MoS Ashwini Choubey*, 2024) (see Figures. 5a and 5b).

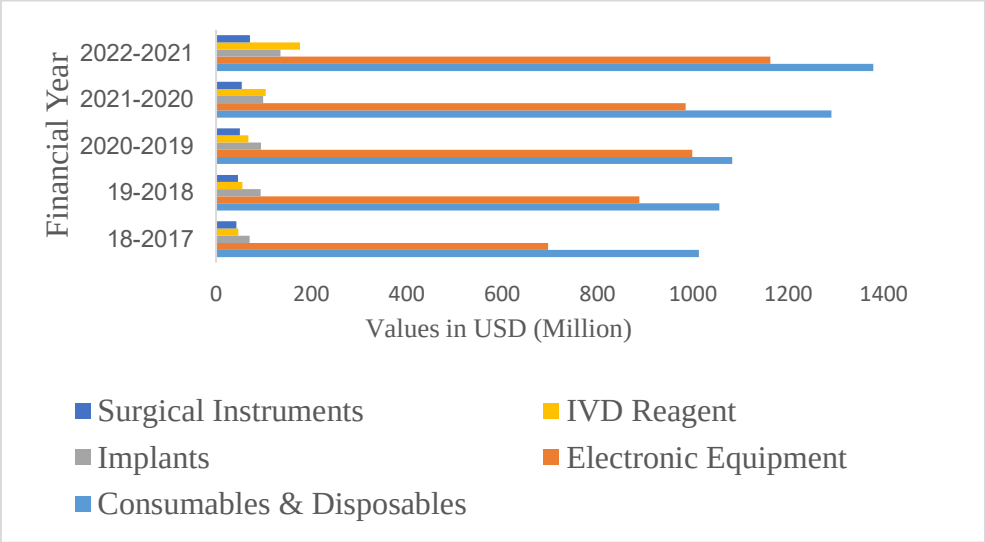

Figure 5a. Category Wise Export of Medical Devices (Source: Engineering Export Promotion Council of India-EEPC, India (*Final Report, Survey of Medical Devices Clusters*, 2023))

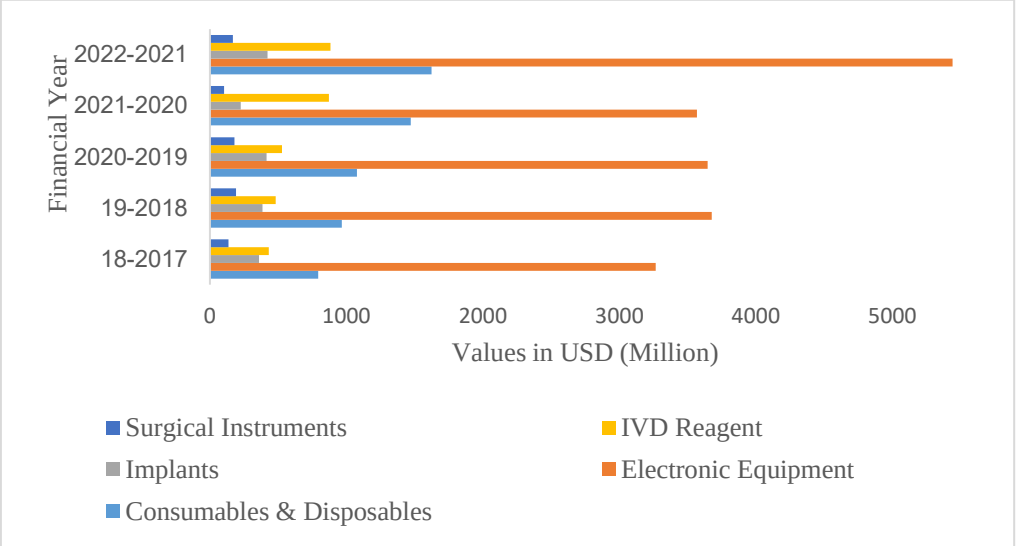

Figure 5b. Category Wise Import of Medical Devices (Source: Engineering Export Promotion Council of India-EEPC, India (*Final Report, Survey of Medical Devices Clusters*, 2023))

The market share of medical devices in India mainly comprises: a) medical instruments and appliances (market share of 34%), out of which 20% are Indigenous manufacturers, and 80% are importers, b) diagnostic imaging devices (market share of 31%), out of which 34% are indigenous manufacturers and 66% are importers c) consumables and implants (market share of 19%), out of which 50% are indigenous manufacturers and 50% are importers; and d) patient aids and others (market share of 16%), out of which 25% are indigenous manufacturers and 75% are importers *(Deloitte, NATHEALTH Medical devices making in India-a leap for Indian healthcare*, 2016) (see Figure 6).

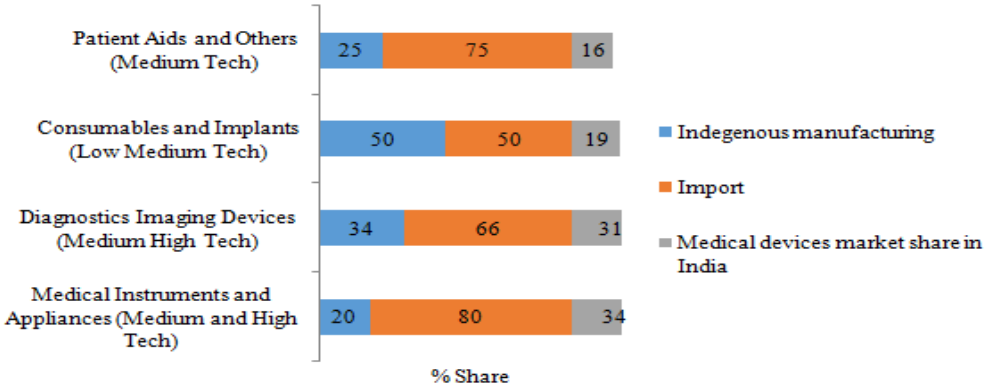

Figure 6. Market share (%) with respective manufacturing and importing of significant categories of medical devices in India (Source: Deloitte, Medical Devices Making in India - A Leap for Indian Healthcare (*Deloitte, NATHEALTH Medical devices making in India-a leap for Indian healthcare*, 2016))

Factors contributing to these imports' reliance include limitations in high-end technology, inadequate access to raw materials for manufacturing, and insufficient infrastructure and testing facilities to produce devices meeting an international standard. In response, efforts to reduce import dependency and foster self-reliance in the medical devices sector, Govt. of India has taken several flagship initiatives such as 'Make in India,' 'Start-up India,' 'Production Linked Incentive' (PLI), 'Foreign Direct Investment' (FDI) Scheme and setting up of 'Medical Devices Parks' which have catalysed investments and spurred innovation and new product development in the MedTech space. However, in the growing MedTech sector, more innovations are envisaged with every passing year by using advanced technologies like artificial intelligence (AI), machine learning (ML), internet of things (IoT), block chain, 5G, 3D printing in manufacturing medical devices such as smart wearable devices, implants, imaging devices, cardiovascular devices, and minimally invasive devices, etc., for which the regulatory compliances of medical devices are evolving, making a way ahead for comprehensive healthcare to all. Since medical device regulations are dynamic and vary from country to country, specific compliances are becoming increasingly stagnant worldwide.

The manuscript embarks a critical literature review of the regulatory framework's evolution governing medical devices, aiming to elucidate how pivotal changes have shaped the current regulatory landscape and influenced the medical devices industry in India. In addition, a brief comparison of the regulatory model specific to the EU and U.S. with India's counterpart is featured to thoroughly understand the regulatory approval across their geographic territories.

2. Importance of Stringent Medical Device Regulations

In numerous countries globally, the necessity for rigorous regulation emerged mainly to facilitate patients' access to high-quality, safe, and effective medical devices while preventing access to harmful items. Stringent medical device regulations are imperative due to the critical role these devices play in public healthcare, encompassing diagnosis, monitoring, and treatment. Ensuring that medical devices meet their intended use, are effective, and guarantee the safety of patients and operators is paramount. In this regard, reports of adverse incidents linked to faulty medical devices accentuate the necessity for rigorous regulations to enhance safety, quality, and design standards. Instances such as the faulty Acetabular Surface Replacement (ASR) hip implants from Johnson & Johnson in India, affecting thousands of patients due to metal degeneration and subsequent health complications, illustrate the risks associated with inadequate regulation *(innovation, J. J, 2010)*. Similarly, recalls of Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D) devices highlight the life-threatening consequences of premature device failures *(Medtronic Recalls Implantable Defibrillators, U.S. Food & Drug Administrator*, 2023). Recognising these safety concerns, the World Health Organization (WHO) has urged member states to establish guidelines for good manufacturing practices (GMP) and regulatory standards, as well as surveillance systems to ensure

the quality, safety, and efficacy of medical devices (*World Health Organization, Good Manufacturing Practices, Health products policy and standards*). With an estimated two million different types of medical devices on the global market, spanning over 7,000 generic device groups, diverse professionals are designing and supplying these devices (*Medical Devices, World Health Organization*). Hence, Stringent Regulation is essential to meet the medical community's and the public's needs, ensuring the safety and efficacy of devices used for medical purposes.

Moreover, it is understood that regulation of medical devices started relatively late in the 1960s and 1970s by observing the possibility of risks of micro-shocks from an electric current through the device (Contardi, 2019). Since then, demand for strict regulation legislation has come into the picture, and many countries have revamped their regulatory systems to support development or innovation and introduce preventive compliances to strengthen the medical device industry.

2.1. Regulatory Authority and Chronology of Medical Device Regulation in India

Medical device regulation in India is governed by the central and state Governments, which are accountable for enforcing the Act. The Central Drugs Standard Control Organization (CDSCO) serves as the principal Central Licensing Authority (CLA) and is overseen by the Drugs Controller General of India (DCGI). The State Licensing Authority (SLA), led by the State Drug Controller, collaborates with the CLA to develop policies and ensure consistent enforcement of regulations nationwide to protect citizens' lives.Significant technological developments in evolving Indian medical device regulation are herewith summarised (see Table 1).

Table1. Emergence of medical devices regulation in India

S.No	Major induction	Outcome	Reference
1	Inclusion under the Drugs and Cosmetics Act (DCA), 1940	Initially, medical devices were regulated as “drugs” under the DCA, 1940. On November 13th, 1982, an amendment to the DCA redefined “drugs” to include medical devices, subjecting them to the DCA's regulatory framework.	(*Act 68 of 1982: Drugs and Cosmetics*, 1982)
2	Introduction of requirements for manufacturing premises	On February 22, 1994, particular specifications for industrial facilities for the production of medical devices were announced.	(*Schedule M-III in Drugs and Cosmetics Rules, 1945 By Govt. of India Notification No. G.S.R. 109(E), w.e.f. 22.2*, 1994)
3	Guidelines for import/manufacture and clinical trials	On January 20, 2005, rules were issued for acquiring authorisation to import or manufacture novel pharmaceuticals and executing clinical studies. These regulations encompass medical devices categorised as "drugs."	(*Medical devices regulation in India: tracing its evolution to get cues on its future development*, 2020)
4	Notified medical device	The Health Ministry notified 10 sterile devices on October 6, 2005	(*S. O. 1468(E), (October 06, 2005)* 2012)
5	Sale, manufacture, and import of medical devices	On October 7, 2005, the Health Ministry delegated the DCGI the authority to sell, manufacture, and import the 10 notified devices. Subsequently, regulations for importing these 10 devices were implemented on March 1st, 2006.	(*Guidelines for import and manufacture of medical devices.* , 2018; *G.S.R. 627 (E), October 07, 2005, 2005*)

6	Proposal of Medical Devices Regulation Bill (MDRB), 2006	In 2006, the Ministry of Science and Technology proposed the MDRB 2006 to consolidate legislation concerning medical devices, establish the Medical Device Regulatory Authority of India (MDRA), and implement risk-based classification of medical devices.	(Updates on the Medical Device Regulations in India, September 1, 2009, Pacific Bridge Medical, U.S, 2009)
7	Introduction of Medical Devices Rules (MDR), 2017	Framed in conformity with the GHTF framework, the MDR 2017 classified medical devices based on risk and intended use, provided guidelines for licensing and clinical investigation and aimed to encourage Indigenous manufacturing of devices and implemented from January 1, 2018.	(Gazette of India notification, G. S. R. 78(E), January 31, 2017, 2017)
8	Draft Medical Devices (Safety, Efficacy, and Innovation) Bill, 2019	The proposed bill aimed at regulating all locally manufactured and imported medical devices, introducing fines and penalties for non-compliance, and emphasising the need for a national register of medical devices.	(*The Medical Devices Bill, explained*, 2019; "NITI Aayog plans to bring all medical devices under one regulatory regime," 2019)
9	Draft Bill for New Drugs, Medical Devices, and Cosmetics, 2022 July 8, 2022	Proposed to ensure the safety, effectiveness, and compliance with international standards of all drugs and cosmetics, including medical devices. It included provisions for setting up advisory boards, medical device testing facilities, mandatory registration of manufacturers, tax breaks for exports, and a single-window clearance system.	(New Drugs medical devices and cosmetics Bill,)
10	Approval of National Medical Devices (NMD) Policy, 2023 May 2, 2023	Aimed to providing a comprehensive framework for sustained growth and development of the medical device sector, focusing on regulatory streamlining, infrastructure development, R&D and innovation, investment attraction, and human resource development	(*National Medical Devices Policy*, 2023)
11	National Single Windom System (NSWS) January 1, 2024	NSWS Portal was developed independently from the existing Online System for Medical Devices portal for four applications (MD-1, MD-12, MD-16 and MD-39) under Medical Devices Rules 2017 and made life from January 1, 2024.	(*Launching of National Single Window System (NSWS) Portal*, 2024)
12	Periodic Safety Update Reports (PSUR) concerning marketing authorization. (MA) of medical devices/ IVD, March 19, 2024	Submission of online applications of PSURs w.r.t MA of Medical Devices/ In-vitro Devices has been functional through the online medical devices portal system.	(*Marketing Authorization of Medical devices: in vitro devices.*, 2024)

These developments underscore the evolving regulatory landscape in India, reflecting efforts to enhance the safety, quality, and accessibility of medical devices while fostering growth and innovation in the sector.

Since January 1, 2018, after MDR-2017 was operationalised across the country, different amendments have been formulated to facilitate ease of merchandising and availability of quality medical devices in India. (see Table 2). It is recommended by various stakeholders in the industry, manufacturers, healthcare providers, think tankers, policymakers, innovators, and start-ups, that all medical devices should be regulated in a phased manner to ensure that business continuity is not disrupted at all. Based on this recommendation, risk-based classification of the medical devices has been further categorised and notified, meaning that not all

medical devices follow the exact regulatory approval mechanism. For example, all non-sterile and non-measuring devices classified as class A medical devices are considered minimal risk and shall be registered (in both cases, either for manufacture or import) through an identified online portal established for the purpose (see Figure 10).

The Ministry of Health and Family Welfare, Government of India, has issued a notification to classify all medical devices as medications, as per S.O. 648 (E) dated 11.02.2020, under sub-clause (iv) of clause (b) of section 3 of the drugs and Cosmetics Act, 1940, effective from 01.04.2020 ("Gazette of India notification, S.O. 648(E)," 2020). In this regard, the CDSCO has issued G.S.R. 102 (E) dated 11.02.2020 to regulate medical devices in a phased approach. This ensures that business continuity remains unaffected by the licensing regime implementation, which commences on 01.10.2022 for class A and B medical devices and on 01.10.2023 for class C and D medical devices ("Gazette of India notification, G.S.R. 102 (E)," 2020). Before coming to the licensing regime on the date described above, sufficient time has been given to the manufacturer/importer to register their products (30 months for classes A and B and 42 months for classes C and D) so that they may ensure an uninterrupted supply of such medical devices across the country (See Table 3). The process of registration is a significantly simple process and subjective in nature. Once the application is submitted, the registration process will generate a file number, which must be included on the label before marketing.

Manufacturers and importers who fail to secure registration by October 1, 2022 (for classes A and B) and October 1, 2023 (for classes C and D) must either cease operations of the specified medical devices until they obtain the necessary registration or face potential penalties for violating the DCA and MDR. It has been determined that if an existing importer or manufacturer of Class A or Class B medical devices submits an application to the CLA or SLA for an import or manufacturing license under the provisions of MDR, 2017, on or before 30.09.2022, the application will be considered valid. The importer or manufacturer may persist in importing or manufacturing the specified devices for a maximum of six months from the issuance date of this order or until the CLA or SLA renders a decision on the application, whichever occurs first *(Central Drugs Standard Control Organization, Ministry of Health and Family Welfare notification number: F. No. 29/Misc/03/2022-DC (257), dated 30.09.2022 Regulation of all Class A & B Medical Devices under Licensing regime, w. e. f. 01.10.2022, as per G.S.R. 102(E) dated 11.02.2020)*

In the meantime, the CLA can use this period to build the necessary infrastructure and more notified bodies (earlier, only six notified bodies were approved till 31st July 2019, which is increased to 14 notified bodies by 15th Feb 2024 *(Central Drugs Standard Control Organization, Ministry of Health and Family Welfare notification number: F. No. 29/Misc/3/2017-DC (288),* List of notified bodies registered with CDSCO under MDR-2017 dated 31.07.2019; List of notified bodies available on the Online System for Medical Devices portal of CDSCO). Also, approval should be obtained to establish more medical device testing laboratories (MDTL) to carry out tests or evaluations of a particular medical device on behalf of the manufacturer. Presently, 61 MDTL labs have been registered with CDSCO to test different devices/reagents/IVDs as per the provision of MDR-2017 (*List of Testing Laboratories available on the Online System for Medical Devices portal of Central Drugs Standard Control Organization, Ministry of Health and Family Welfare*). This will enrich the device integrity in India and address critical issues such as notified bodies' capacity, compliance resources' availability, and potential delays in product certification.

Table 2. Brief Amendments in MDR-2017

S.No	Gazette Notification Number	Date of implement	Amendment Rules	Explanation	Reference
1	G.S.R. 729 (E)	1st August 2018	Medical Devices (Amendment) Rules, 2018	The manufacturer shall submit a performance evaluation report for in-vitro diagnostic medical devices to the SLA or CLA for the appropriate risk-based classification of MD/IVD.	(*The Gazette of India notification, G.S.R. 729 (E).* 2018)
2	G.S.R. 224 (E)	18th March, 2019	Medical Devices (Second Amendment) Rules, 2019	Modification of Environmental Requirements for the Production of Medical Devices Condom Annexure- A of the Fifth Schedule of MDR, 2017	(The Gazette of India notification, G.S.R. 224 (E). 2019)
3	G.S.R.787(E)	16th October, 2019	Medical Devices (Fifth Amendment) Rules, 2019	Testing laboratories of State and central governments shall be exempt from the necessity of accreditation by NABL for two years.	(Gazette of India notification, G.S.R. 787 (E). 2019)
4	G.S.R. 102 (E)	11th February, 2020	Medical Devices (Amendment) Rules, 2020	Expanded the 37 categories of notified medical devices within the scope of the DCA. All medical equipment, excluding these categories, must be registered with the CLA via a designated online portal commencing April 1, 2020.	(Gazette of India notification, G.S.R. 102 (E). 2020)
5	S.O. 648 (E)	11th February, 2020	Medical Devices Definition	Extended the definition of medical devices to include software, accessories, appliances, and others from April 1, 2020	(Gazette of India notification, S.O. 648 (E), 2020)
6	G.S.R. 918 (E).	31st December, 2021	Medical Devices (Amendment) Rules, 2021	Distinct apparatus Identification of all medical devices authorized for sale, distribution, or import (draft)	(Gazette of India notification, G.S.R. 918 (E). ," 2021)
7	G.S.R. 174 (E).	4th March, 2022	Medical Devices (Second Amendment) Rules, 2022	Include the United Kingdom in the list of territories that offer medical device importers the granting of an import license without undergoing clinical investigation.	(Gazette of India notification, G.S.R. 174 (E). 2022)
8	G.S.R. 356 (E).	18th May, 2022	Medical Devices (Third Amendment) Rules, 2022	Suspension and cancellation of licence	(Gazette of India notification, G.S.R. 356 (E), 2022)
9	G.S.R. 450 (E).	15th June, 2022	Medical Devices (Fourth Amendment) Rules, 2022	The Biological Safety (TSEs/BSE) Certificates are unnecessary if the source originates from an animal species in a specified country.	(Gazette of India notification, G.S.R. 450 (E). 2022)

10	G.S.R. 754 (E).	30th September, 2022	Medical Devices (Fifth Amendment) Rules, 2022	Registration certificate for the sale, stocking, exhibition, offering for sale, or distribution of medical devices in India, including in vitro diagnostic medical devices.	(Gazette of India notification, G.S.R. 754 (E). 2022)
11	G.S.R. 777 (E).	14th October, 2022	Medical Devices (Sixth Amendment) Rules, 2022	Exemption of non-sterile and non-measuring Class A medical devices from the licensing regime (registration required for manufacture/importation)	(Gazette of India notification, G.S.R. 777 (E). 2022)
12	G.S.R. 409(E).	2nd June, 2023	Medical Devices (Amendment) Rules, 2023	Creation of a state medical devices testing laboratory designated by the state government under sub-regulation (3) of rule 19 of MDR-2017	(Gazette of India notification, G.S.R. 409 (E). 2023)

Table 3. Timeline for the execution of medical devices regulation in India

Risks based classification	Voluntary registration	Mandatory registration	License regime	Reference
Class A and B	01.04.2020 to 30.09.2021	01.10.2021 to 30.09.2022	w.e.f. 01.10.2022	(Gazette of India notification, G.S.R. 102 (E), 2020)
Class C and D		01.10.2021 to 30.09.2023	w.e.f. 01.10.2023	
Class A medical devices (non-sterile and non-measuring)		14.10.2022 onwards	Exemption from licensing regime (only registration required for manufacture/import) w.e.f. 14.10.2022 to till date	(Gazette of India notification, G.S.R. 777 (E), 2022)
Class A medical devices (sterile and measuring)		Not applicable	w.e.f. 01.10.2022 comes into the licensing regime	(Gazette of India notification, G.S.R. 102 (E), 2020)

2.2. Classification of Medical Devices in India: Underlying Criteria and Risk Class

Based on the intended use of the device, associated risks, and other parameters outlined in the MDR-2017, the CLA of India classifies medical devices into four risk classes (see Figure 7), namely class A (further divided into non-sterile & non-measuring and sterile & measuring), B, C and D. The basic principles governing these classifications include the following:

- The purpose of the device.
- Combination devices/accessories/components.
- Software is classified in the same class as its associated device.
- Calibrators utilised with a reagent are categorised within the same classification as the reagent.
- Devices with numerous designated functions are categorised according to their primary function.
- If a device is designed for use in conjunction with another device, the categorisation rules shall be applied independently to each device.
- If disparate devices of varying classifications are amalgamated into a singular device or kit, the most rigorous regulations corresponding to the higher classification of the integrated device shall be enforced.

These principles guarantee the precise categorisation of medical devices according to their intended use and related dangers, enabling suitable regulatory control and ensuring patient safety.

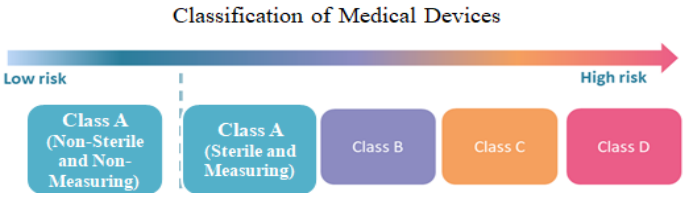

Figure 7. Risk-based Classification of Medical Devices

2.3. Regulatory Approval of Medical Devices in India: Manufacture and Import

Each unique category of medical devices adheres to a designated regulatory pathway, guaranteeing suitable approvals and compliance with safety and quality criteria during the registration procedure. The SLA will issue a manufacturing or loan license to produce notified Class A (sterile and measuring) and Class B devices. In contrast, the CLA will issue the manufacturing or loan licenses for Class C and Class D devices. (see Figure 8a, 8bi, 8bii). These licenses possess perpetual validity unless suspended, cancelled, or renewed, contingent upon the payment of the license retention fee before the expiration of five years from the date of issuance. No assessment of the quality management system by a registered notified body for the manufacturing site is required before issuing a manufacturing license or loan license to sell or distribute Class A medical devices (excluding non-sterile and non-measuring devices).According to the stipulations of MDR-2017 (Sub Rule 4 (i and ii) of Rule 20), an audit of the manufacturing site is not a compulsory prerequisite for the issuance of a manufacture or loan license for the sale or distribution of Class A medical devices (excluding non-sterile and non-measuring devices) ("G. S. R. 78(E), January 31, 2017," 2017). A quality management system (QMS) audit of a class A device manufacturing site (excluding non-sterile and non-measuring devices) is mandated by the registered notified body as outlined in the third schedule of MDR-2017 and must be conducted within one hundred and twenty days from the date the state licensing authority issued the license. Furthermore, mandatory registration for class A devices (non-sterile and non-measuring) necessitates the submission of a declaration from the manufacturer affirming that the proposed device adheres to the essential principle's checklists for safety and performance and complies with the relevant standards applicable to such devices. This self-explanatory endeavor addresses potential health risks, emphasizing risk management, design controls, and corrective and preventive actions (CAPA) to ensure patient safety is never compromised in any clinical setting. At its discretion, the relevant licensing authority may cancel or suspend the registration number, either entirely or for specific medical devices if malpractice is reported or if the applicant fails to adhere to any provisions of these regulations.

Conversely, for Class B medical devices, the manufacturing site must adhere to the QMS criteria outlined in the fifth schedule, and a registered notified body must verify this compliance through an audit prior to the issuance of a license. Furthermore, CLA will conduct an inspection of the manufacturing site following the assessment of necessary documentation for Class C and D, in accordance with Chapter IV, manufacture of medical devices for sale or distribution, MDR-2017.
Firstly, an applicant can apply for a test license for manufacturing a small quantity of medical devices for the purpose of clinical investigation, test, evaluation, examination, demonstration, or training to make three consecutive test batches (in case both or either predicate devices are available or not in India) with a validity of three years. It is noted that if there is no predicate device available in India against the proposed device, meaning that it comes under the scope of investigational medical devices, the applicant/innovator can initiate the regulatory approval by applying test license (MD-12) application followed by clinical investigation (MD-22); permission to manufacture (MD-26) and commercial manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device (see Figure 8bi). On the other hand, if

predicate devices are earlier approved in India against the proposed device, the applicant can directly apply for the test license (MD-12) followed by a manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device (see Figure 8bii). Moreover, import licenses of Class A (sterile and measuring), Class B, Class C and Class D have been granted from CLA with perpetual (see Figure 9). Despite that Class A devices (non-sterile and non-measuring), registration is solely required for manufacturing and import on the online portal of medical devices, as depicted in Figure 10.

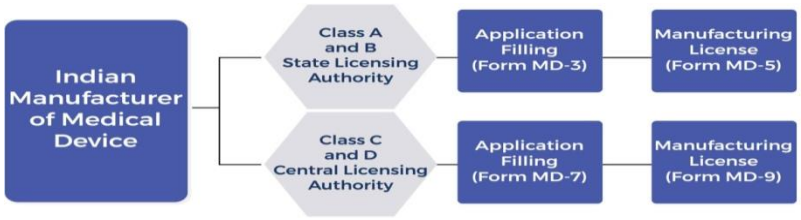

Figure 8a. Role of SLA and CLA to grant manufacturing medical devices

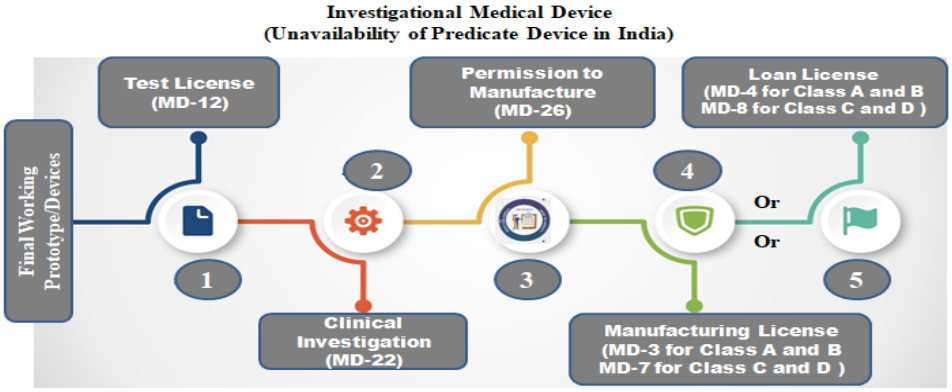

Figure 8bi. Workflow of sequence of the application for the grant of manufacturing/loan license of all medical devices (other than Class A non-sterile and non-measuring) in India. If there is no predicate device available in India against the proposed device, meaning that it comes under the scope of investigational medical devices, the applicant/innovator can initiate the regulatory approval by applying test license (MD-12) application followed by a clinical investigation (MD-22); permission to manufacture (MD-26) and commercial manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device

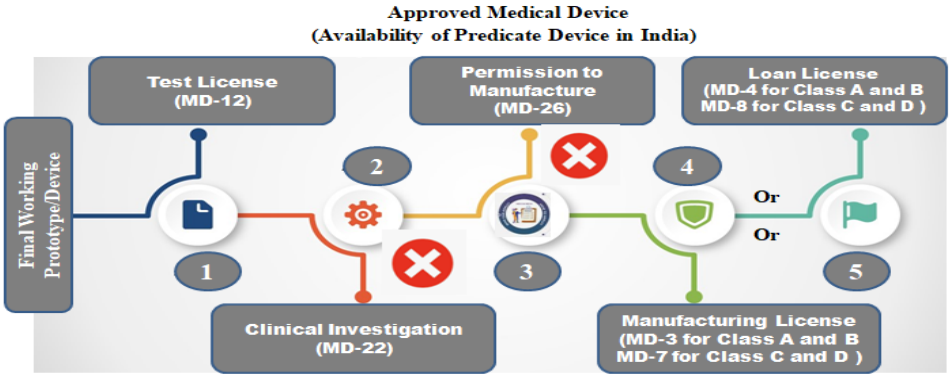

Figure 8bii. The sequence of the application for the grant of manufacturing/loan licenseof approved devices in India. If the proposed devices are earlier approved in India, the applicant can directly apply for the test license (MD-12) followed by a manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device. In this regard, there is no requirement to get the application for clinical investigation (MD-22) and permission to manufacture (MD-26), which is indicated with a red Cross mark

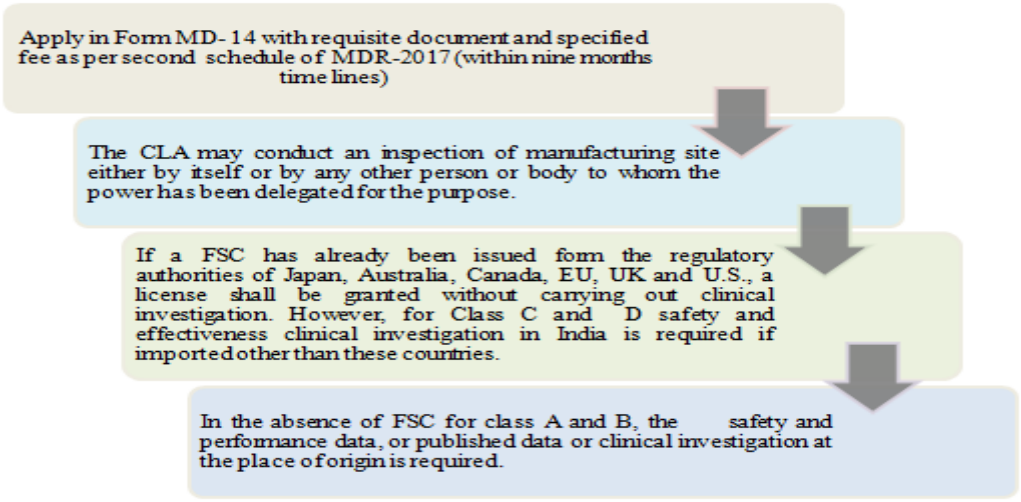

Figure 9. Schematic representation of approval of import license of medical devices (other than Class A non-sterile and non-measuring) in India

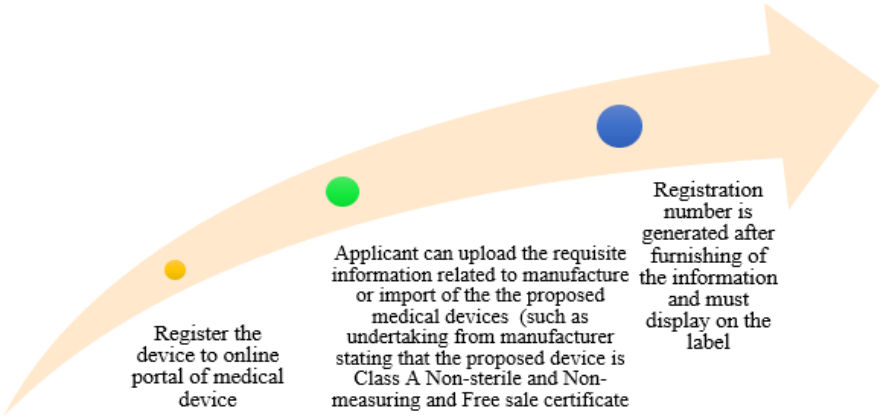

Figure 10. Illustration of the registration process of Class A (non-sterile and non-measuring) medical devices in India for the purpose of manufacturing and import into India

2.4. Regulatory Pathway for Conducting Clinical Investigation of Medical Device

A clinical investigation is a sequence of events involved in running a clinical trial or a research study that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct, and record keeping of the study. Clinical investigation is mandatory for manufacturing the investigational medical device (class A -sterile and measuring, B, C, and D) and importing the medical device (class A -sterile and measuring, B, C, and D) from countries other than the U.S, UK, Japan, EU, Australia, and Canada, the applicant can submit form MD-22 to the CLA, along with the necessary information listed in the seventh schedule of the MDR-2017.Upon receipt of the requisite requirements, including Institutional Ethics Committee (IEC) approval and clinical study plan, the CLA may grant permission in Form MD-23 (based on the subject expert committee recommendation), allowing the clinical investigation to commence. In addition, the clinical investigation must be registered with the clinical trial registry of India (CTRI) before enrolling participants, and the first participant must be enrolled within one year of grant permission.

However, without carrying out clinical investigation, the import license for all risk-based classified medical devices (other than class A non-sterile and non-measuring)from the U.S, UK, Japan, EU, Australia, and Canada may be granted based on the fact that the proposed device had been marketed for at least two years in these countries. CLA is satisfied with the data of safety, performance, and pharmacovigilance of the device (see Table 4). These studies are essential for obtaining regulatory approval

of the device. Applicants must submit annual status reports on each clinical investigation to the CLA detailing the ongoing, completed, or terminated status of the study.

Table 4. Condition for conducting the clinical investigation of medical device

Medical Device	Purpose	Clinical Investigation	Condition
based risk-based classified Medical Devices (other than Class A – non-sterile and non-measuring)	Manufacture	Mandatory	Investigational medical device (No predicate device available)
		Not applicable	Subsequent equivalent predicate device (demonstrate concerning intended use, design, types of specimens, materials of construction,and technological characteristics underlying the working principle) available in India
	Import	Waive off	▪ Medical Devicesimported from countries U.S, UK, Japan, EU, Australia, and Canada ▪ Remain marketed for at least two years in these countries ▪ CLA is satisfied with the data on the safety, performance and pharmacovigilance of the device
		Mandatory	Medical devices approved and marketed in other than the U.S, UK, Japan, EU, Australia, and Canada.
			Investigational medical devices

Further, there are two types of clinical investigations conducted for medical devices, namely:

1. **Pilot Clinical Investigation:** A pilot clinical investigation is an initial study conducted on a small group of patients to gather specific information about the device before initiating the pivotal clinical study. It is exploratory and aims to assess feasibility, evaluate preliminary device performance, examine eligibility criteria, ascertain possible harm, study device mechanism, and validate outcome measures or surrogate outcomes. Pilot studies do not provide support for specific therapeutic claims but are crucial for informing the design and conduct of subsequent pivotal studies.
2. **Pivotal Clinical Investigation:** Pivotal clinical investigations are definitive or confirmatory studies conducted in a larger population to gather evidence supporting the safety and effectiveness of the medical device intended for use and conclusive. Pivotal studies are conducted following pilot investigations and must demonstrate the safety and effectiveness of the device in the intended Indian patient population.

2.5. Post Marketing Surveillance (PMS) Reporting in India

PMS is a continuous process of monitoring and collecting data (containing both complaints and adverse events) on the safety and performance of medical devices after being released to the market. The document provides a proactive and systematic process for manufacturers to collect and analyse post-market data in terms of reporting procedures for AE (adverse events) complaints received, SUSAR (Serious Unexpected Suspected Adverse Reactions) reports, PSUR (Periodic Safety Update Report), CAPA and FSCA (Field Safety Corrective Action).

ISO 20416:2020 is an international standard for Post-Market Surveillance (PMS), aligning with ISO 13485, which emphasizes quality criteria for medical devices, and ISO 14971, which primarily addresses safety, security, and risk connected with the use of medical devices. The manufacturer or importer of the investigational medical device (MD-27 or MD-29 holder) is permitted

to submit the Periodic Safety Update Report (PSUR) to the competent licensing authority i.e., CLA from the date of the device's market launch. This report must be submitted biannually for the initial two years, followed by annual submissions for the subsequent two years.

MD-27/MD-29 holders can conduct post-marketing clinical investigations for testing the safety and performance, which covers the two significant reporting such as:

i. CAPA: It is a system that all medical device companies must establish to identify quality-related concerns, examine their core causes, and execute remedial and preventative steps to prevent recurrence. The five principles of the CAPA technique are: a) Detection (issue identification), b) Investigation and root cause analysis, c) Proposed correction, d) Implementation, and e)Verification of effectiveness.

ii. FSCA: It is a measure that manufacturers may undertake for technical or medical justifications to mitigate or diminish the risk of severe occurrences, including fatalities, associated with the use of a medical device that has been commercialized.

The PSUR submission of investigational medical devices (approved for manufacturing or import in India) requires the documents (Checklist for PSUR Submission of New Medical Devices approved for Manufacturing or Import in India). Moreover, to sustain a better risk-benefit ratio of medical devices, the Government of India (Indian Pharmacopoeia Commission) has approved the commencement of the materiovigilance programme of India (MvPI). MvPI aims to systematically collect data on medical device-related adverse events and scientifically analyze them to aid in regulatory decisions and recommendations on the safe use of medical devices (see Figure 11). Sixteen medical devices have been recalled from the Indian market since the MvPI was launched, and many more are under systematic review (Product Recall, CDSCO). The medical device-associated adverse events (MDAE) under the aegis of MvPI create awareness among healthcare professionals about the importance of MDAE reporting in India.

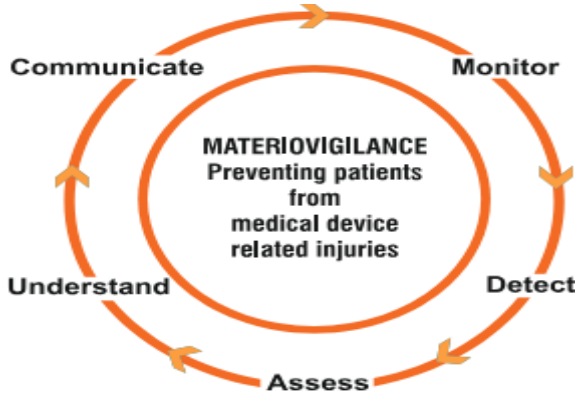

Figure 11. MvPI, evidence-based recommendations on the safety of medical devices

3. Comparative Insight of Regulatory Approval: Legislative Landscape and Historical Development in the U.S. and EU

The comprehensive regulatory approval process is intricate, multistep, and region-specific and requires critical assessments by the competent authority. It is also a metaphorical ‘valley of death’ in which most products fail to fulfil the regulatory pathways before being commercially marketed. Each country has stringent regulatory compliances to safeguard and elevate healthcare end users by assuring medical devices' safety, efficacy, and quality. An in-depth analysis of the regulatory landscape governing medical devices in India regulated by the Indian Apex body, namely CDSCO, with a focus on comparing it with the regulatory frameworks in the European Union-Medical Device Regulation (EU-MDR) and the United States-Food and Drug

Administration (U.S.-FDA) in terms of device classification, pre-market approval requirements, post-market surveillance, and quality management systems.

3. 1. Chronology of Medical Device Regulation in the U.S

The historical development of medical device regulation in the USA has been framed (see Figure 12). These legislative milestones reflect the evolution of medical device regulation in the USA, aiming to include risk-based classification of all medical devices, post-market surveillance, improvements in the premarket reviews system, and certification of facilities for ensuring the safety, effectiveness, and quality of medical devices throughout their lifecycle (A History of Medical Device Regulation & Oversight in the United States; Medical Device & Diagnostics).

3.2. Chronology of Medical Device Regulation in the European Union

The evolution of medical device regulation in the EU reflects the commitment to ensuring medical device safety, quality, and performance while promoting innovation and competitiveness in the healthcare industry. The chronology of medical device regulation in the EU can be outlined as follows, with significant milestones as per European Commission Medical Devices Directives (European Commission Medical Devices Directives) (see Figure 13a and 13b).

1. European Economic Community (EEC) Directives (1970s-1990s): The first directives related to medical devices were introduced by the EEC in the 1970s, focusing on specific product categories such as implants, active implantable medical devices, and in vitro diagnostic medical devices. These directives aimed to establish common standards for safety and performance across member states.
2. Medical Devices Directives (MDD) (1990s-2010s): The MDD comprised three directives: the Active Implantable Medical Devices Directive (AIMDD), the Medical Devices Directive (MDD), and the In Vitro Diagnostic Medical Devices Directive (IVDD). These directives harmonised regulations for medical devices within the EU and established the CE marking process for market approval.
3. Revision and Amendment of MDD (2010s): In response to technological advancements and concerns about the effectiveness of the existing regulatory framework, the EU began revising and amending the MDD. This led to the introduction of the Medical Devices Regulation (MDR) and the IVDR in 2017.
4. Medical Devices Regulation (MDR) (2017): The MDR replaced the MDD and introduced more stringent requirements for approving, manufacturing, and marketing medical devices in the EU. It expanded the scope of regulation to include certain products that were previously unregulated or considered low-risk, such as software and aesthetic devices. The MDR also established stricter conformity assessment procedures and increased transparency and traceability requirements.
5. In Vitro Diagnostic Medical Devices Regulation (IVDR) (2017): The IVDR replaced the IVDD and introduced similar enhancements to the regulatory framework for in vitro diagnostic medical devices. It imposed stricter requirements for clinical evidence, performance evaluation, and post-market surveillance to ensure the safety and effectiveness of these devices.
6. Transition Period (2017-2021): Following the adoption of the MDR and IVDR, a transition period was established to allow manufacturers and other stakeholders to adapt to the new regulatory requirements. During this period, devices could continue to be placed on the market under the existing directives, but they would eventually need to comply with the new regulations.

7. Implementation (2021 and beyond): The transition period for the MDR ended on May 26, 2021, marking the full implementation of the regulation. Manufacturers must now comply with the MDR's requirements for all new devices seeking market approval or renewal of existing certifications. The IVDR's transition period is set to end in May 2022.

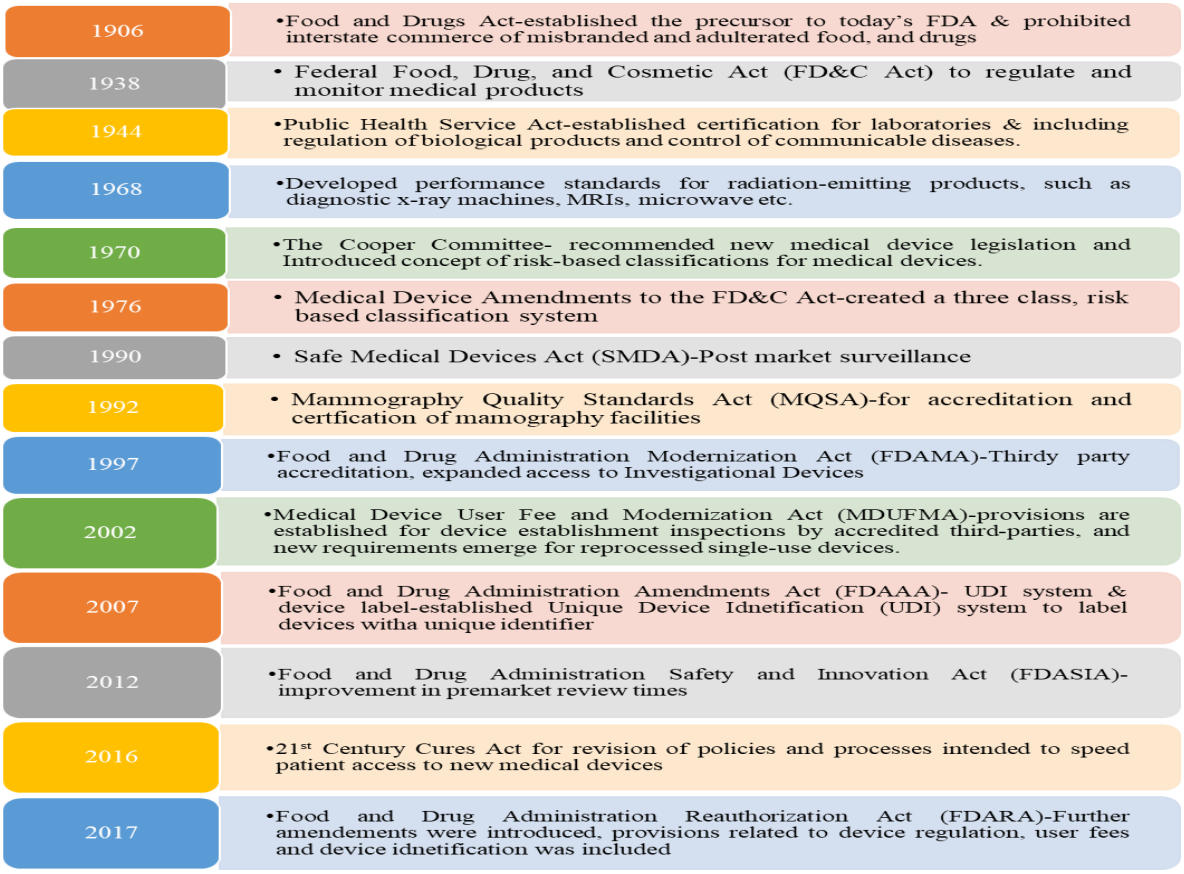

Figure 12. Chronology of medical device legislation in the U.S.

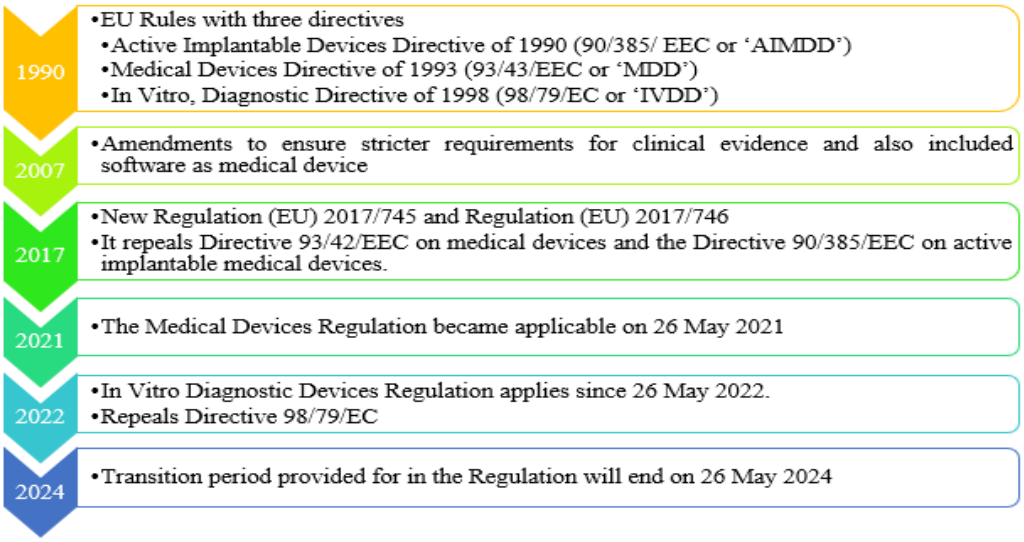

Figure 13a: Chronology of medical device legislation in EU

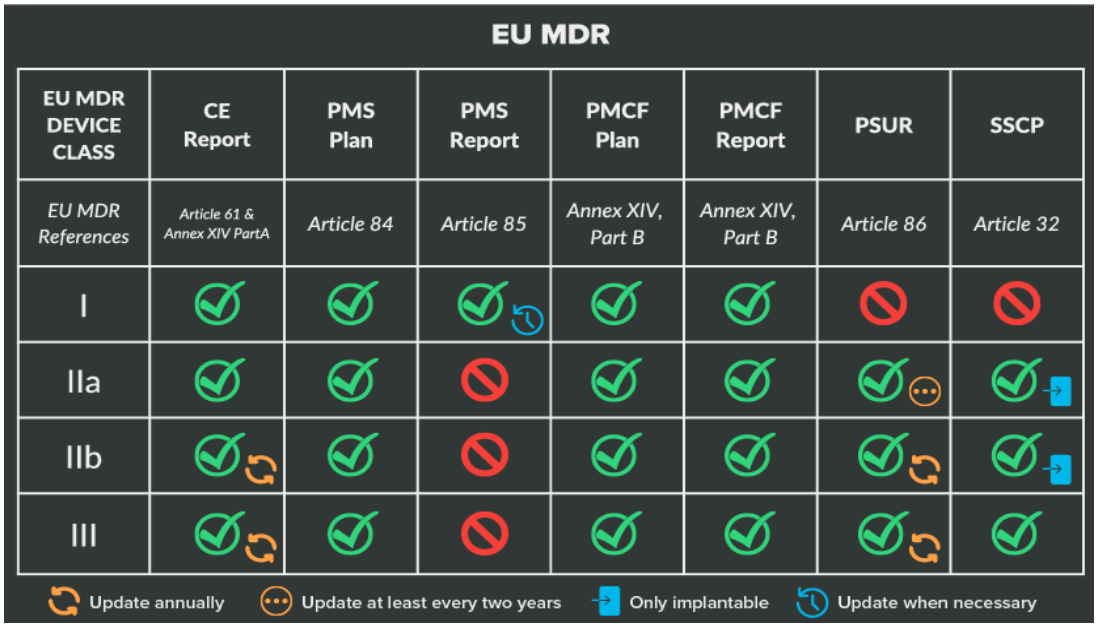

Figure 13b. Major compliances of EU MDR for all risk-based classification of medical devices

3.3. Assessment of Distinctness of International Medical Device Regulation: USA versus EU

A comparative description has been summarized (see Table 5) to overview the legal and regulatory requirements in the EU and the US to place a medical device on the market. There are many similarities but significant differences in the requirements concerning clinical evidence and post-market surveillance in the two regions.

Table 5: Resemblance and Differences of USA and EU Medical Device Regulation

Point of Comparison	India	USA	EU
Regulatory body	Directorate General of Health Services, MoH&FW, DCGI under CDSCO	FDA, Department of Health and Human Services	EMA & Registration authorities (RA) of Member State
Assisting bodies	CLA for Class C & Class D Medical Devices, SLA for Class A & Class B medical devices	CDRH-FDA	NCA-EMA
Regulation act/Guidelines	MDR-2017 Through the Drugs & Cosmetics Act 1940	Federal Food Drug and Cosmetic Act (FD & C Act); Food and Drug Administration Safety and Innovation Act 21 CFR Parts 800-1299	Regulation (EU) 2017/745 for medical devices Regulation (EU) 2017/746 for IVDs
Classes of medical devices	Four (Class A, B, C & D)	Three (Class I, Class II and Class III	Four (Class I, IIa, IIb & III)
Standards making body	BIS/ ISO/ IEC	U.S. FDA	ESO such as: CEN, CENELEC, ETSI
QMS or Applicable standards (mandatory)	ISO 13485:2016	QSR 21CFR Part 820 (Similar to ISO13485:2016 but not same)	ISO 13485 or as per applicable in 94/42/EEC Regulation (EC) No 765/2008

Assessment of technical data	Notified bodies under CDSCO	CDRH	CE marking of conformity
Language	English	English	Official union language as determined by member state
Submission format	Electronic through Online System for Medical Devices portal	Electronic using CDRH Portal - eSTAR.	Electronic

4. Discussion

Since 1st January 2018, when Indian medical device regulations came into existence, it went through dedicated deliberation among the healthcare authorities and different stakeholders to adopt a holistic approach for including medical devices/diagnostics falling in the category of low-risk to high-risk, under license regime, while maintaining high standards of quality, tolerability, and effectiveness. Futuristic healthcare innovations like wearables, telemedicine, multiplex pathogenic kits, drug-eluting patches, breath analyser-based diagnostic techniques, immersive technologies (such as Virtual Reality (VR), Augmented Reality (AR), Mixed Reality (MR), and Extended Reality (XR)) based diagnostics primarily using on surgery and anatomy-related subjects against particular disease/conditions, organoid bioprinting technology that uses 3D printing to create tissue models that mimic the structure and function of human organs, Volatile Organic Chemicals (VOCs) based detection of specific cancer, Nanoscale Point of Care (POC)/Point Of Detection (POD) device, drug delivery system and others are emerging and accordingly MDR is evolving. Such dynamic technological progress has led to a transformative surge in medical device regulation, propelling the rise of new and innovative medical devices. Presently, no specific regulation addresses these futuristic technologies-based medical devices. However, clinical decision-making tools using Artificial Intelligence (AI), Machine Learning (ML), and Internet of Things (IoT) algorithms have highlighted the urgency of devising new regulations to address the transformation. Accordingly, an amendment in the MDR, 2017 was introduced under gazette notification S.O. 648 (E) for extending the scope of medical devices, including software-integrated medical devices/Software as Medical Devices (SaMD) in the regulatory regime ("Gazette of India notification, S.O. 648(E)," 2020). Considering clinicians are highly dependent on SaMD for diagnosing, preventing, monitoring, and treating diseases, it is extremely important to have compliance with standards and statutory guidelines that are still evolving.

During Covid-19 onwards, CDCSO issued a notification regarding risk-based classification of medical devices pertaining to Personal Protective Equipment (PPE), masks (2-ply, 3-ply, surgical, N-95), RNA and DNA extraction kits, viral transport media, viral reagents, liquid chemical sterilant/high-level disinfectants, rapid antigen/antibody-based and RT-PCR kits for testing of Covid-19to facilitate import, manufacture, sale and distribution and clinical investigation for effective pandemic management. The results of this spotlight are that till 20.06.2022, 262 IVD kits have been approved, out of which 102 kits are indigenously manufactured (*PCR Kits approved for testing of Covid-19* 2022). Earlier, India broadly relied on the import of PPE and masks. However, it is the outcome of the regulatory initiative that India has become the second-largest manufacturer of PPE in the world within a short period, and more than 600 companies in India are certified to produce PPEs today, whose global market worth is expected to be over $92.5 billion by 2025 (*Investment Opportunities in Textiles and Apparel Textiles and Apparel; Textiles Committee* 2020). On the other hand, IVD kits for diagnosis of COVID-19 have been processed as a high priority for accelerated approval for marketing in India to support companies that are either developing the kits or importing the existing ones already approved by the U.S. FDA or EMA. Data requirements for clinical performance evaluation may be abbreviated, deferred, or waived on a case-to-case basis depending on the type and nature of diagnostics kits, existing data on the product, and evidence of available clinical performance evaluation data of such kits in the country of origin. Moreover, applications to

manufacture/import such IVD kits for testing, evaluation, and further use in performance evaluation may be processed on priority within seven working days. Many CDSCO-designated labs have been updated to conduct a performance evaluation of such IVD kits during the Covid-19 health emergency without compromising the quality of the products in India.

Hence, recognising the myriad instruments affecting individual and animal health, the government must extend regulations to this rapidly evolving realm, as a handful of medical devices are currently regulated only.

5. Conclusions

The review delves into the dynamic landscape of the Indian medical device market statistics, legislative changes, and government initiatives to significantly increase the manufacture of medical devices. Indian regulators have transitioned from a flexible, need-based approach to a systematic and stringent regulatory framework aimed at ensuring the effectiveness and safety of medical devices. Despite having huge import dependency, India has made significant strides, ranking fourth in Asia while maintaining high standards of quality, safety, and efficacy. Further, a comparative analysis of the regulation processes for medical devices in India, the US, and the EU highlights variations in terms of CE marking, risk-based classification, validity period, post-market surveillance, traceability and other conditions and specifications that adhere to ensure that products are made at par with global standards. As a part of a comprehensive strategy towards strengthening the healthcare system in India in alignment with the vision of Viksit Bharat 2047 (Develop India 2047), the introduction of medical devices (Amendment) rules in 2020 towards more stringent regulations is a welcome move in this direction. Conformity to these regulations will ensure that products are made at par with international quality.

In parallel, some recommendations have been proposed, such as creating a comprehensive database for information on all recalled medical devices. This could also be the next important step for ensuring patient safety. Similarly, creating a QR code-unique to a particular medical device/IVD, conveying necessary information on the nature, date, and validity of applicable license (manufacturing/import), intended use, instructions for use (IFU), etc. will be a critical step towards traceability of medical devices in the long run. Additionally, establishing a database with information on all devices approved so far (predicate devices), along with their technical details, will be highly beneficial to the innovators working in the MedTech innovation space so that innovators can smoothly enforce the regulatory directive. To achieve success, it is also necessary to consolidate the enforcement mechanism called materiovigilance, which is used for identifying, collecting, reporting, and analyzing adverse events associated with medical devices to improve patient safety by preventing the recurrence of adverse events.

Further, all concerned stakeholders and knowledge partners shall work closely together with the regulator as a public-private partnership (PPP) model so that it will address and mitigate the challenges faced by innovators. In this view, the government has introduced a dedicated public relations office (PRO) with a mandate to act as an interface catalyser between the regulator and its stakeholders, including the general public, for the exchange and dissemination of information to foster the disposal of grievances, provide complete details regarding regulatory prerequisites for the commercialisation of products, clarification about MDR and handholding assistance to investors in various phases of the business life cycle as per the existing focus on the "Invest India/Make in India initiative". This initiative demonstrates the government's commitment to enabling quality medical device manufacture in India and positioning the country as a global hub for medical devices that are reliable and trustworthy.

Author Contributions

The manuscript is conceptualized and formulated by several authors with their specific contributions. Garima Singhal and Aarti Sahu conducted an extensive literature review to gather relevant information on medical device regulations in India, the

United States, and the European Union. Their work involved identifying existing frameworks and understanding gaps in the current landscape.

Deepak Kumar Gupta, **Meeta Mukherjee Verma**, and **Jyoti Batra** contributed significantly to the core content of the regulatory framework, discussed key challenges, and highlighted current systems' drawbacks and potential strategies and solutions to address these issues effectively.

Rupak Kumar and **Suchita Markan** played a crucial role in shaping the paper's overall framework and conceptualization. They were also responsible for the meticulous proofreading of the manuscript, ensuring clarity, coherence, and academic rigor throughout the paper.

Conflicts of Interest

The authors declare that the review was comparatively analyzed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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List of Abbreviations

MoH&FW: Ministry of Health and Family Welfare; **DCGI:** Drugs Controller General of India; **PMA:** Premarket Approval; **CDSCO:** Central Drugs Standard Control Organisation; **NCA:** National Competent Authorities; **IVD:** In-vitro Diagnostics; **EMA:**European Medicines Agency; **CDRH:** Centre for Devices and Radiological Health; **QR:** Quick Response**;** **FDA:** Food and Drug Administration; **FSC:** Free Sale Certificate; **ESO:** European Standards Organization; **CEN:** European Committee for Standardization; **CENELEC:** European Committee for Electrotechnical Standardization **ETSI:** European Telecommunications Standards Institute; **BIS:** Bureau of Indian Standards; **ISO:** International Organization for Standardization; **IEC:** International Electrotechnical Commission; **CDRH:** Centre for Medical Devices and Radiological ; **PMA:** Post Market Approval ; **PMS:** Post Market Surveillance; **PSUR:** Periodic Safety Update Report; **CLA:** Central Licensing Authority; **SLA:** State Licensing Authorities; **PMSR:** Post Market Surveillance Report; **PMCI:** Post Market Clinical Investigation;**MDR:** Medical Device Regulation; **PMCF:** Post-market clinical follow-up; **CER:** Clinical Evaluation Report; **PER:** Performance Evaluation Report; **PAS:** Post-Approval Studies; **AE:** Adverse events; **MvPI:** Materiovigilance Programme of India; Health; **QSR:** Quality System Regulation; **QMS:** Quality Management System **TSE:** Transmissible Spongiform Encephalopathies; **BSE:** Bovine Spongiform Encephalopathy;**NABL:** National Accreditation Board for Testing and Calibration Laboratories; **MD:** Medical Device; **DCA:** Drug and Cosmetic Act; **CE:** ConformitéEuropéenne or European conformity; **PMCF:** Post-Market Clinical Follow; **SSCP:** Summary of safety and clinical performance.

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