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Comparative Study of Indian Medical Devices Regulations with Selected Countries: A Systematic Review

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ABSTRACT:
The global medical device industry has seen significant growth in recent years, highlighting the need for coherent and harmonized regulatory frameworks. India, recognizing this demand, introduced the Medical Devices Rules (MDR), 2017 under the Drugs and Cosmetics Act, 1940 to enhance safety, effectiveness, and quality of medical devices. This paper compares India's evolving regulatory system with six established regimes: those of the USA, UK, EU, Canada, Australia, and Japan. Key aspects examined include device classification, approval pathways, Quality Management Systems (QMS), clinical evidence requirements, labeling, unique device identification (UDI) implementation, regulation of software as medical devices (SaMD), and post-market surveillance. While India's framework exhibits strengths—such as adopting a risk-based classification system and initiating regulatory capacity-building—challenges remain in areas like innovation, facilitation and technical infrastructure. The study concludes with policy suggestions to strengthen India's regulatory ecosystem and support its ambitions to become a global hub for medical devices.

1. Introduction:

The three integral pillars of modern healthcare technology are drugs, vaccines, and medical devices. Among these, medical devices encompass a vast and evolving category—from basic bandages and syringes to highly sophisticated technologies that incorporate bioinformatics, nanotechnology, engineered cells, and artificial intelligence [1]. Medical devices play a pivotal role in screening, diagnosis, treatment, rehabilitation, and continuous health monitoring, thereby contributing significantly to disease prevention and improved patient outcomes [2]. The World Health Organization defines a medical device as any instrument, apparatus, equipment, machine, implant, reagent intended for in vitro use, software, or material, whether used alone or in combination, that is designed by the manufacturer for a medical application. [3] These devices are indispensable for a range of medical procedures—from routine interventions to complex surgeries and palliative care—across home settings, clinics, dental and optical care centers and advanced hospitals. [3] There are currently

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more than 2 million types of medical devices categorized into over 7000 generic groups globally. [3]

1.1 Global Medical Device Market: Size and Growth Drivers

The global medical device industry has witnessed substantial expansion. According to Ernst & Young's 2023 report *Pulse of the MedTech Industry*, the sector was valued at USD 587.6 billion in 2023, having grown at a Compounded Annual Growth Rate (CAGR) of ~8.3% between 2019 and 2023. It is projected to reach USD 897 billion by 2028, driven by digital transformation, changing disease patterns, and evolving healthcare systems. [4]

1.1.1 Overview of Global MedTech market

The global MedTech industry is divided into four segments.

(1) **Therapeutic Devices:** The largest segment, encompassing cardiology, orthopedics, oncology, dental, and hearing aids. It includes AI-enabled devices, robotic-assisted systems, and minimally invasive tools [4]

(2) Research and Equipment: Comprising analytical tools and life sciences instrumentation for next-generation therapies, including cell and gene therapy [4]

(3) Non-Imaging Diagnostics: Includes in-vitro diagnostic (IVD) devices for molecular testing, immunoassays, and home-based diagnostics like Continuous Glucose Monitoring (CGM) [4]

(4) Imaging Diagnostics: Covers Magnetic Resonance Imaging (MRI), Computed Tomography (CT), X-ray, ultrasound, and Positron Emission Tomography (PET) scanners. The integration of Artificial Intelligence/Machine learning (AI/ML), portability, and energy efficiency are key trends. [4]

Table 1: Global Medical Device Market by Segment (in USD Billion) [7]

Type of Medical Devices	2015 (in USD Bn)	2020 (in USD Bn)	2030 (Estimated) (in USD Bn)	CAGR (2020-2030)
Electronics & Equipment	172.63	216.72	500.96	8.74%
Disposable & Consumables	119.43	159.08	412.75	10.00%
Surgical Instruments	42.54	55.25	136.86	9.49%
IVD Reagents	35.41	44.81	105.39	8.93%
Implants	31.89	39.32	87.42	8.32%
Total	401.89	515.19	1243.38	9.21%

1.1.2 Global MedTech market by region

The global market is dominated by the United States (40%), followed by Europe (25%), and Japan (15%). [5] Emerging economies such as India and Thailand are experiencing rapid growth. Despite India's significant manufacturing base, per capita expenditure on medical devices is just USD 3, compared to the global average of USD 47, and USD 415 in the United States of America (USA). [5] By segment, cardiology devices represent the largest global market share. [6] Worldwide demand is rising, and global market growth is estimated at CAGR 9.21% from 2020 to 2030, with disposables and surgical instruments among the fastest-growing categories. [7]

Effective regulation is essential to ensure that medical devices of all types adhere to recognized standards of safety, quality, and performance. From simple gloves to complex implants, medical devices require risk-based classification, stringent regulatory oversight, and clinical performance validation [8]. The World Health Assembly Resolution WHA67.20 (2014) emphasized that effective regulatory systems are critical to strengthening health systems and improving outcomes.

1.2 Overview of Indian Medical Device Industry

India ranks as the 4th largest MedTech market in Asia and is among the top 20 markets globally, expected to reach USD 50 billion by 2030 at a CAGR of 16.4% [9]. The sector includes domestic firms that manufacture low-end consumables and implants, alongside multinational companies (MNCs) producing high-end products through acquisitions or greenfield ventures [10]. India's

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product base spans from catheters, cannulas, syringes, and stents to intraocular and orthopedic implants [10].

According to Association of Indian Medical Device Industry (AIMED), the medical device market size was USD 12 billion in 2023–24.[11] In Financial Year (FY) 2023–24, electronic equipment and disposables/consumables collectively Contributed to about 82.5% of India's total trade in the medical device sector, encompassing both imports and exports. The domestic market is primarily divided into five segments: electronic equipment holds the largest share at 56%, followed by disposables and consumables (26.5%), in-vitro diagnostics (8.1%), implants (7.1%), and surgical instruments (2.3%). [4] Despite recent growth, India continues to face a significant mismatch between the domestic demand and production of medical devices, with approximately 70–80% of its requirements being met through imports. [10]

1.2.1 Exports from India

India exported USD 2.9 billion worth of medical devices in FY 2021–22, up 15.5% YoY, with a CAGR of 8.43% from 2019–20 to 2021–22[7]. The USA (21.6%) is India's top export market, followed by China, Germany, France, and Singapore. 'Disposables and consumables' accounted for 47.1%, while electronics had a 39.8% share, and InVitro Diagnostic (IVD) reagents contributed 6%. Export of implants and surgical instruments also showed strong growth [7].

1.2.2 Imports into India

India remains a net importer, with imports valued at USD 8.5 billion in 2021–22, growing 36.8% from the previous year [7]. China is the largest supplier (19.4%), followed by the USA and Germany. Imports are dominated by electronics and equipment (63.7%), followed by disposables (19%) and IVD reagents. Although some import categories like implants saw a downturn in 2020–21, most recovered in 2021–22[7].

1.2.3 Government Initiatives to Strengthen the Indian MedTech Sector

Designated as a "Sunshine Sector" within the 'Make in India' initiative, the Indian government has undertaken various policy reforms aimed at boosting the sector's global competitiveness [1]

These include:

(1) Medical Devices Rules (MDR), 2017 and the National Medical Devices Policy, 2023, aimed at streamlining regulation [4].

(2) Product Link Incentive (PLI) Scheme (2020) to promote domestic manufacturing and reduce import dependency [6].

(3) Medical Device Parks with shared infrastructure in states like Andhra Pradesh, Telangana, and Tamil Nadu [4].

(4) International Medical Device Regulatory Forum (IMDRF) Membership (2024) aligns Indian regulation with global standards [4].

(5) 100% FDI allowed in the sector, with over USD 3.7 billion inflow between 2000–2024[10].

This study offers a detailed comparative assessment of India's medical device regulatory system with those of the United States of America (USA), European Union (EU), Canada, United Kingdom (UK), Japan, and Australia. Through an examination of both structural and procedural aspects, the analysis identifies India's regulatory advancements as well as critical gaps requiring attention. The objective is to critically assess the alignment of India's regulatory system with global standards, identify existing gaps, and propose strategic policy reforms. These recommendations aim to enhance regulatory efficiency, foster domestic innovation, and strengthen India's position as a globally competitive hub for medical device manufacturing and innovation.

2. Methodology:

This comparative review is based on secondary data from academic databases (PubMed, SCOPUS, and Google Scholar), government reports, and official websites of national regulatory authorities such as Central Drugs Standard Control Organization, India(CDSCO), Food and Drugs Administration, USA(FDA), Medicine and Healthcare products Regulatory Agency(MHRA), UK, European Union Commission (EU), Health Canada, Therapeutic Goods Administration, (TGA), Australia and Pharmaceuticals and Medical Devices Agency,(PMDA), Japan. Search terms included "Indian Medical Devices Regulation", "Post-Market Surveillance", "Medical Device Approval Process", and "Comparative Regulatory Framework". Relevant documents were reviewed to evaluate classification

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systems, licensing processes, quality management, clinical evaluations, labeling norms, post-market surveillance (PMS), Unique Device Identification (UDI), and digital health regulation.

3. Medical Devices Regulation of India:

In India, the regulatory oversight of medical devices falls under the Drugs and Cosmetics Act, 1940, an act originally designed for pharmaceuticals. Within this framework, medical devices are classified as "notified drugs." Unlike conventional drugs, medical devices integrate multidisciplinary principles from engineering, electronics, materials science, and information technology [1].

The CDSCO, functioning under the Directorate General of Health Services within the Ministry of Health and Family Welfare (MoHFW), acts as India's National Regulatory Authority (NRA) for medical devices [13]. It oversees key regulatory functions, including the approval of manufacturing and import licences, supervision of clinical investigations, formulation of standards, and regulation of the sale and distribution of medical devices. These functions are executed under the provisions of the Medical Devices Rules (MDR), 2017. The MDR was notified via G.S.R. 78(E) on January 31, 2017, and became effective on January 1, 2018, under the Drugs and Cosmetics Act, 1940. [12-14] The rules are designed to align with global regulatory frameworks, and supports national initiatives such as Make in India. [12-15] Structurally, the MDR, 2017 consists of 12 chapters, 8 schedules, and 43 forms that offer comprehensive regulatory guidance to manufacturers and stakeholders. [15]

3.1 Scope and Categories Regulated under MDR

As per the MDR, the following are classified as medical devices [2]

(a) Devices for internal or external use intended for diagnosis, treatment, mitigation, or prevention of disease or disorders in humans or animals as notified by the government.

(b) Substances or materials designed to affect the anatomical structure or physiological functions of the human body, which may encompass mechanical contraceptives such as condoms and intrauterine devices (IUDs), along with products like disinfectants and insecticidal agents.

(c) Medical products encompassing surgical dressings, sutures, staples, ligatures, and blood collection bags used in clinical or surgical settings.

(d) Substances or materials used for in vitro diagnosis**.**

Initially, a very few medical devices were notified. However, a key development occurred through a notification on 11th February 2020, effective 1st April 2020, whereby all medical devices were brought under regulatory oversight by defining a broad, inclusive definition [2]. According to this, a medical device is:

"All devices including an instrument, apparatus, appliance, implant, material or other article; whether used alone or in combination, including software or an accessory for one or more of the following purposes:
i. Diagnosis, prevention, monitoring, treatment or alleviation of disease
ii. Diagnosis, monitoring, treatment, alleviation or assistance for injury or disability
iii. Investigation, replacement or modification or support of the anatomy or physiological process
iv. Supporting or sustaining life
v. Disinfection of medical devices
vi. Control of conception.

Deadline for obtaining licence for manufacture and import of Class A & B medical device is September 30, 2022 and for Class C & D medical devices is September 30, 2023. [8]

The MDR adopts a risk-based regulatory approach, with perpetual licensing to streamline procedures and reduce administrative burdens [2].

3.1.1 Definition of Medical Devices

(Chapter I, Rule 3(zb), MDR, 2017) [15]

The MDR classifies medical devices to include:

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

(B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings),

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disinfectants and insecticides notified in the Official Gazette under sub-clause (ii);

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

3.1.2 Classification of Medical Devices

(Chapter II, Rule 4, MDR, 2017) [15]

Parameters for classification of Medical Devices and In Vitro diagnostic medical devices are mentioned in First Schedule of MDR, 2017

(a) Classification of Medical Devices [Excluding In Vitro Diagnostic Devices (IVDs)]

Under the Medical Devices Rules, 2017, medical devices (other than IVDs) are classified based on their intended use and associated risk into four categories:

Table 2-A: Classification of Medical Devices (other than IVDs) [15]

Class	Risk Level	Examples
Class A	Low Risk	Surgical gloves, Dental examination kit
Class B	Low to Moderate Risk	Disposable hypodermic needles, Disposable Hypodermic syringes Intravenous sets (IV set)
Class C	Moderate to High Risk	Suture absorbable, Dental Amalgam, Hemodialysis Catheter,
Class D	High Risk	Heart valves, Coronary stents, pacemakers

(b) Classification of *In vitro* Diagnostic Devices (IVDs)

Under the Medical Devices Rules, 2017, IVDs medical devices are classified based on their intended use and associated risk into four categories:

Table 2-B: Classification of *In vitro* Diagnostic Medical Devices [15]

Class	Risk Level	Examples
Class A	Low Risk	Cholesterol analyser in blood, Breath-alcohol test system
Class B	Low to Moderate Risk	Albumin test reagent/kit, Cholesterol test reagent/kit, Hemoglobin test reagent/kit
Class C	Moderate to High Risk	Ribonucleic acid (RNA) Extraction Kits, Deoxyribonucleic acid (DNA) Extraction Kits , C- Reactive Protein (CRP)test reagents/kits
Class D	High Risk	ABO system test reagent/kit, Human Immuno Deficienty Virus (HIV) test reagent/kit

3.1.3 Premarket Approval Processes

(a) Manufacturing Class A & B Devices

(Chapter IV, Rule 20, MDR, 2017) [15]

- The application for a manufacturing licence or loan licence is submitted to the State Licensing Authority using Form MD-3 or Form MD-4, respectively. It must be accompanied by the prescribed fee outlined in the Second Schedule

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and the required documents listed in Part II of the Fourth Schedule of the Medical Devices Rules (MDR).

- Licence is issued in Form MD-5 or MD-6 respectively**.**
- For Class A, a post-licence audit is conducted by notified bodies within 120 days.
- For Class B, the audit is conducted before issuing the licence.

(b) Manufacturing Class C & D Devices

(Chapter IV, Rule 21, MDR, 2017) [15]

- The application is submitted to the Central Licensing Authority through the online portal using Form MD-7 for a manufacturing licence or Form MD-8 for a loan licence, along with the applicable fee as per the Second Schedule and the required documents outlined in clause (ii) of Part II of the Fourth Schedule of the Medical Devices Rules, 2017.
- Licences are issued in Form MD-9 or MD-10 respectively.
- Compliance with International Organization for Standardization (ISO) 13485:2016 Quality Management System (QMS) is mandatory.

3.1.4 Import of Medical Devices

(Chapter V, Rule 34, MDR, 2017)[15]

- Importers must hold an appropriate wholesale or manufacturing licence.
- The application is submitted to the Central Licensing Authority through the online portal using Form MD-14, accompanied by the applicable fee as prescribed in the Second Schedule and the necessary documents outlined in the Fourth Schedule of the Medical Devices Rules.
- Licence is issued in Form MD-15**.**
- Clinical investigation is not mandatory if a Free Sale Certificate has been issued by regulatory authorities in the USA, EU, UK, Canada, Australia, or Japan.

3.1.5 Manufacturing or Import of Novel or Predicate-Free Medical Devices & new In vitro

Diagnostic medical device

(Chapter VIII, Rules 63–65, MDR, 2017) [15]

- Medical devices that lack a predicate or involve a new intended use, target population, material, or significant design modification are classified as investigational medical devices.
- A predicate device refers to a previously approved device—first of its kind—authorized by the Central Licensing Authority for manufacture, sale, or import in India, sharing similar intended use, construction material, and design features with the proposed device.
- A novel (new) in vitro diagnostic (IVD) medical device is one that has not received prior approval in India and requires performance evaluation data.
- A separate permission to market must be obtained from the Central Licensing Authority, based on clinical investigation or performance evaluation demonstrating safety, performance, or effectiveness**.**
- The application for import or manufacture of novel (predicate free) medical device is submitted to the Central Licensing Authority through the online portal using Form MD-26, accompanied by the applicable fee as prescribed in the Second Schedule and the necessary documents outlined in the Fourth Schedule of the Medical Devices Rules.
- Licence is issued in Form MD-27**.**
- The application for import or manufacture new *In vitro* diagnostic medical device is submitted to the Central Licensing Authority through the online portal using Form MD-28, accompanied by the applicable fee as prescribed in the Second Schedule and the necessary documents outlined in the Fourth Schedule of the Medical Devices Rules.

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- Licence is issued in Form MD-29.

Table 3: Summary of Licensing Requirements for Medical Devices in India, as per Medical Devices Rules, 2017 [2, 15]

Licence Type (of MD/IVDs)	**Application Form**[15]	**Licence Issuance Form**	**Processing Timeline**	**Licensing Authority**	**Relevant Regulatory Rule**
Retail Sale of Medical Devices[2, 15]	Form 19 (as per Drugs Rules) [15]	Retail Licence in Form 21 (Drugs Rules) [15]	Typically 3–6 months (no statutory time limit) [15]	State level Drug Licensing Authority (SDLA) [15]	Rule 61(2), Drugs & Cosmetics Rules[2, 15]
Wholesale Distribution of Medical Devices[2, 15]	Form 19 (as per Drugs Rules) [15]	Wholesale Licence in Form 21-B (Drugs Rules) [15]	Usually processed within 3–6 months (not officially specified) [15]	State level Drug Licensing Authority (SDLA) [15]	Rule 61(2), Drugs & Cosmetics Rules[2, 15]
Manufacturing of Class A & B Devices[2, 15] Loan Licence of Class A & B device for Third-party Facility[2, 15]	Form MD-3 [15] Form MD-4[15]	Form MD-5[15] Form MD-6[15]	Class A –(self-certification): 45 days, Class B – (SLA review) Audit by Notified Body (NB): within 90 days of application, Submission of report: within 30 days of inspection, Grant of licence: within 20 days after getting report [15]	State Licensing Authority (SLA) [15]	Rule 20(4) for Class A & Rule 20(6) for Class B of MDR,2017[2, 15]

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Manufacturing of Class C & D Devices[2, 15] Loan Licence of Class C & D device for Third-party Facility[2, 15]	Form MD-7 [15] Form MD-8[15]	Form MD-9[15] Form MD-10[15]	Scrutiny by CLA: within 45 days of application, inspection of site: within 60 days of application, Grant of licence after getting report by CLA: within 45 days[15]	Central Licensing Authority (CLA) [15]	Rule 25(1) of MDR, 2017[2, 15]
Test Licence for manufacture for Clinical Investigation, Test etc. for Class A, B, C & D[2, 15]	Form MD-12[15]	Form MD-13[15]	Processing time is 30 days[15]	Central Licensing Authority (CLA) [15]	Rule 31(3) of MDR, 2017[2, 15]
Import of Medical Devices (All Classes) [2, 15]	Form MD-14[15]	Form MD-15[15]	Processing may take up to 9 months[15]	Central Licensing Authority (CLA) [15]	Rule 36(1) of MDR,2017[2, 15]
Import for Clinical Investigation, Test etc.[2, 15]	Form MD-16[15]	Form MD-17[15]	Timeline is 30 days[15]	Central Licensing Authority[15]	Rule 41(1) of MDR,2017[2, 15]
Import by Govt. Hospitals[2, 15]	Form MD-18[15]	Form MD-19[15]	No fixed timeline defined[15]	Central Licensing Authority (CLA) [15]	Rule 42(2) of MDR,2017
Import for Personal Use[2, 15]	Form MD-20[15]	Form MD-21[15]	Typically processed within 7 days[15]	Central Licensing Authority (CLA) [15]	Rule 43(3) of MDR,2017[2, 15]
Permission to conduct Clinical Investigation of investigational Medical Devices[2, 15]	Form MD-22[15]	Form MD-23[15]	Permitted within 90 days[15]	Central Licensing Authority (CLA) [15]	Rule 52(1) of MDR,2017[2, 15]

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Permission to conduct Clinical performance evaluation of new *in vitro* diagnostic medical device [2, 15]	Form MD-24[15]	Form MD-25[15]	Permitted within 90 days[15]	Central Licensing Authority (CLA) [15]	Rule 59(5) of MDR,2017[2, 15]
Permission to manufacture/import of medical device not having predicate [2, 15]	Form MD-26[15]	Form MD-27[15]	Timeline is 120 days, further 30 days[15]	Central Licensing Authority (CLA) [15]	Rule 63(2) of MDR,2017[2, 15]
Permission to manufacture/import of New In Vitro Diagnostic Device[2, 15]	Form MD-28[15]	Form MD-29[15]	Timeframe is 90 days, further 30 days[15]	Central Licensing Authority (CLA) [15]	Rule 64(2) of MDR,2017[2, 15]

3.1.6 Quality Management System (QMS) Requirements

(Fifth Schedule, MDR, 2017) [15]

As per the Fifth Schedule of the Medical Devices Rules (MDR), 2017, manufacturers of both medical devices and in vitro diagnostic (IVD) devices must implement a Quality Management System (QMS) to ensure product safety and minimize risks. This QMS must comply with ISO 13485:2016: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes[16], the globally recognized standard for medical device manufacturing.
The QMS covers the entire lifecycle of the device — from design and development to testing, packaging, labeling, and after-sales servicing. Manufacturers are required to adhere to these QMS standards. Failure to comply may lead to suspension or cancellation of the manufacturing licence.

3.1.7 Labeling Requirements

(Chapter VI, Rules 44 to 48, MDR, 2017) [15]

The MDR mandates that certain particulars must be printed in indelible ink on the label, shelf pack**,** and outer packaging of a medical device. These include:

1. **Device Identification:** The name of the medical device and a description sufficient to determine its intended purpose.
2. **Manufacturer Information:** Name and address of the manufacturer must be clearly stated.
3. **Quantity Details**: The package should indicate the quantity in metric terms (weight, volume, measure, or unit count), along with the total number of devices in the pack.
4. **Dates**: The date of manufacture and expiry or shelf life should be mentioned. For sterile items, the sterilisation date may be considered as the manufacturing date.
5. **Special Contents**: If the device contains medicinal or biological substances, this must be declared.
6. **Batch/Lot Number**: A unique identification such as "Lot No.," "Batch No.," or similar prefixes must be included.
7. **Storage and Handling**: Any specific instructions for storage or handling should be provided if needed.
8. **Sterility Information**: Where applicable, the label should indicate if the device is sterile and mention the method of sterilisation.
9. **User Warnings**: Any necessary precautions or warnings for the user must be clearly displayed.

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10. **Single-use Indication**: If the device is for one-time use, this should be specified.
11. **Physician Samples**: Promotional samples must carry the statement: "Physician's Sample—Not to be sold."
12. **Manufacturing Licence**: For products made in India, the manufacturing licence number must appear with appropriate prefixes such as "Mfg. Lic. No." or "M. L."
13. **Imported Devices**: If essential information is not pre-printed, it should be provided through stickering, including import licence number, importer's name and address, manufacturing site, and date of manufacture.

Recognised symbols from BIS or ISO may be used in place of corresponding text. For small-sized devices where full labelling is not feasible, essential elements such as device name, purpose, manufacturer details, quantity, date, batch number, single-use indication, and licence number must still be visible. Devices intended exclusively for export are exempt from certain Indian labelling requirements and must adhere to the labelling regulations of the importing country.

Unique Device Identification (UDI)

Although the Unique Device Identification (UDI) [3] system was initially set to be fully implemented by January 1, 2022, the Ministry of Health and Family Welfare has postponed its complete rollout. Further clarification and detailed guidelines are still awaited regarding the specific implementation criteria.

The UDI system is comprised of two main elements:

Device Identifier (DI): This is a static component that identifies the device's specific model or version. It is typically linked with a Global Trade Item Number (GTIN).

Production Identifier (PI): This section varies depending on the product and includes key manufacturing details such as the serial number, batch or lot number, software version (if relevant), and dates of manufacture or expiry.

3.1.8 Clinical Investigation of Medical Devices and Clinical Performance Evaluation of New In vitro Diagnostic Devices

(Chapter VII, Rules 49 to 62, MDR, 2017) [15]

A clinical investigation refers to the systematic study of an investigational medical device on human participants to assess its safety, performance, or effectiveness. Under the MDR, such an investigation is a prerequisite for the manufacturing or import of investigational devices intended for sale in India.

A clinical performance evaluation is a structured assessment of data conducted to confirm that a new *In vitro* diagnostic (IVD) device performs as intended. Approval for manufacturing or importing a new IVD device requires prior evaluation as a mandatory step.

Application Process for Clinical Investigation of Investigational Medical Devices

- To initiate a clinical investigation for a medical device, the sponsor must file an application with the Central Licensing Authority using Form MD-22, accompanied by the necessary documents outlined in the seventh schedule of the Medical Devices Rules, 2017 (MDR).
- Upon review and approval, permission is granted in Form MD-23.

The MDR outlines two categories of clinical investigations:

Pilot Clinical Investigation: This is the initial human study conducted to gather critical preliminary information about the medical device, which is necessary before proceeding to large-scale trials.

Pivotal Clinical Investigation: A detailed and conclusive study designed to generate comprehensive evidence regarding the device's safety and performance for its proposed clinical use.

Application Process for Clinical Performance Evaluation of New *In vitro* Diagnostic (IVD) Devices:

- The sponsor is required to apply to the Central Licensing Authority using Form MD-24 to obtain approval for conducting a clinical performance evaluation.
- This application must include the applicable fee as specified in the second schedule, along with all relevant documents as per Rule 59, Sub-Rule (3), properly signed by the sponsor.

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- Upon review and satisfactory evaluation of the application, the authority issues the approval in Form MD-25.

Table 4: Conditions for exemptions for clinical trials for Investigational Medical Devices and New *in vitro* diagnostic medical device as per Medical Devices Rules, 2017[15]

Parameter	Investigational Medical Device	New *In vitro* Diagnostic Medical Device
Use Case	In cases where no predicate device is available—especially for serious or life-threatening conditions, public health emergencies, or diseases lacking effective treatment options—the Central Drugs Standard Control Organization (CDSCO) may, at its discretion, abbreviate, defer, or waive the requirement for animal or clinical data. Such decisions are made by the Central Licensing Authority based on an evaluation of necessity, public interest, and the available scientific evidence. [15]	In circumstances where no approved *In vitro* diagnostic (IVD) device exists—especially for life-threatening conditions, public health emergencies, or diseases without an established diagnostic solution—the Central Licensing Authority has the discretion to abbreviate, postpone, or waive the requirement for clinical performance data based on the urgency and available scientific justification. [15]
Class A Devices	Data from clinical investigations can be exempted unless deemed necessary by CDSCO[15]	Clinical performance evaluation data may be exempted unless deemed necessary by CDSCO[15]
Drug-Device Combination	Toxicology and other data may be relaxed if drug is already approved in India with sufficient safety data[15]	Expedited approval for COVID-19 kits; foreign-approved test kits can approach DCGI directly. [15]
Foreign Approvals	Clinical investigation data may be waived if approved and marketed for 2+ years in UK, USA, Australia, Canada, or Japan[15]	CDSCO may waive/abbreviate local clinical performance evaluation based on available global data; expedited review for critical tests[15]

3.1.9 Post-Marketing Clinical Investigation & Post-Marketing Surveillance of investigational Medical Devices [15]

(Seventh Schedule, MDR, 2017) [15]

Post-marketing clinical investigation: While certain clinical studies may not be required at the time of a medical device's initial approval, the Central Licensing Authority (CLA) retains the right to request additional investigations post-approval. It is the study other than surveillance performed after marketing approval has been given to the medical device. These post-marketing clinical studies can serve a variety of purposes, such as assessing long-term safety, evaluating interactions with pharmaceuticals, or conducting large-scale outcome trials aimed at measuring endpoints like mortality and morbidity. Such investigations contribute significantly to enhancing the overall understanding of a device's clinical performance and safety in real-world settings. [15]

Post-Marketing Surveillance : According to the Medical Devices Rules (MDR), 2017—specifically Schedule 7, Rule 3—Post-Marketing Surveillance (PMS) plays an important role in the lifecycle monitoring of investigational medical devices after they are introduced into the Indian market. As part of the PMS framework, manufacturers or importers are required to submit Periodic Safety Update Reports (PSURs) to the CLA. These reports must include any new safety data, summaries of patient exposure, changes in international regulatory status, and proposed amendments to product labeling aimed at improving user safety. [15] For higher-risk devices classified under Class C and Class D, PSUR submission is mandatory at six-month intervals during

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the first two years following market approval. Thereafter, reports must be submitted on an annual basis for the subsequent two years. The CLA, in the interest of public health, holds discretionary authority to extend or modify these reporting timelines if warranted. Each PSUR must be filed within 30 calendar days following the end of the respective reporting period. In instances where a Suspected Unexpected Serious Adverse Event (SUSAE) is identified, stakeholders are required to notify the licensing authority no later than 15 calendar days from the initial receipt of the event information.

3.1.10 Post-Market Surveillance and the Materiovigilance Programme of India (MvPI): Ensuring Medical Device Safety [16]

Post-market surveillance (PMS) refers to the continuous monitoring of a medical device's quality, performance, and safety after it becomes commercially available. Also referred to as medical device vigilance, this process is essential for maintaining patient safety and ensuring that devices perform as intended in real-world conditions.

The main aim of Materiovigilance Programme of India (MvPI) is to collect data on medical device related adverse events systematically and scientifically analyze them to aid in regulatory decisions and recommendations on safe use of medical devices being made using data generated from India. The programme is meant to monitor medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders. In India, the Materiovigilance Programme of India (MvPI) was initiated to oversee and ensure the post-marketing safety of medical devices. [16] Launched with the formal approval of the Ministry of Health and Family Welfare on July 6, 2015. Indian Pharmacopoeia Commission (IPC) works as National Coordination Centre (NCC). Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram acts as National Collaboration Centre, National Health System Resource Centre (NHSRC), New Delhi, acts as Technical support partner and Central Drugs Standards Control Organization (CDSCO), New Delhi, supporst MvPI. [16]While reporting of adverse events by device manufacturers is not yet mandatory in India, MvPI promotes voluntary reporting and actively involves a wide range of stakeholders. These include healthcare providers, clinical and biomedical engineers, hospital equipment managers, pharmacists, nurses, technicians, and even patients, to ensure timely reporting of medical device-associated adverse events (MDAEs).[16] Reports can be submitted using the Medical Device Adverse Event Reporting Form, which is available on the IPC's official website (www.ipc.gov.in) [16]. The program represents a critical step toward developing a structured and responsive PMS system that aligns with global standards and supports evidence-based regulatory decisions.

Table 5: Time framed of Adverse Event Reporting for Medical Devices in India as per Medical Devices Rules, 2017[15, 16]

Reporter	What to Report	Reported To	Timeline for Reporting
Entities involved in the medical device supply chain—including Marketing Authorization Holders, manufacturers, importers, and distributors—are accountable for regulatory compliance	Any suspected, unforeseen, and serious adverse event or incident must be reported. This includes, but is not limited to, the following scenarios: Fatal outcomes (deaths), Serious injuries or health deterioration, Device malfunctions that could lead to harm, any corrective or preventive	(1)National Regulatory Authority: CDSCO (2) National Coordination Centre: Indian Pharmacopoeia Commission (IPC) [16]	The incident should be reported within 15 calendar days from the date it is brought to the attention of the responsible party.

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and post-market obligations. [15]	actions undertaken, including product recalls[15]		
User Facilities (e.g., hospitals, clinics) [15]	- Deaths - Serious injuries - Malfunctions[15]	National Regulatory Framework for Medical Devices: (1)National Regulatory Authority**:** CDSCO (2) National Coordination Centre (NCC): Indian Pharmacopoeia Commission (IPC) [16] **(3)** Marketing Authorization Holder (MAH): The organization granted permission to market a medical device in India, accountable for fulfilling post-market surveillance requirements, including the prompt submission of adverse event reports. [16]	Serious events must be reported within 15 calendar days from the date they come to the reporter's attention. In the case of non-serious events, reporting should be completed within 30 calendar days of becoming aware of the incident.

***3.1.11 Medical Devices Recall*:**

(Chapter XI, Rule 89, MDR, 2017) [15, 16]

If a manufacturer, importer, or authorized agent becomes aware of a safety concern associated with a marketed device, they are obligated to initiate a product recall**.** According to the severity, recalls are classified in to Type 1, Type 2 & Type 3 Recalls. [16] Type 1 recall includes a situation in which use of recalled device would cause serious adverse health effects or may even cause death. Type II recalls includes a situation in which use of the recalled devices may cause temporary adverse health consequences or the probability of serious adverse health effects are low and Type III recalls include use of recalled device will not likely to cause any adverse effects. Such hazard based classification systems can be formulated in countries intending to initiate a Post-Market Surveillance Programme. [16] This process involves the immediate removal of the device from the market and prompt communication with patients, healthcare professionals, and regulatory bodies outlining the rationale for the recall. Furthermore, appropriate corrective and preventive actions must be documented and reported to the competent authority to ensure mitigation of any potential public health risks.

[15]

Table 6: Classification of recalls of devices according to the severity of adverse events [15, 16]

Recall Types	**Severity of adverse events associated with recalled device.**
Type 1 [16]	A situation where there is a reasonable likelihood that using or being exposed to a recalled device could lead to serious adverse health effects or possibly death.
Type II [16]	A situation in which using or being exposed to a recalled device might result in temporary adverse health effects, with the likelihood of serious health consequences being minimal.

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Type III [16]	A scenario where the use of, or exposure to, a recalled device is unlikely to cause any adverse health effects. Such hazard-based classification systems can be developed by countries planning to implement a Post-Market Surveillance Programme.

3.1.12 Digital Health and Software as a Medical Device (SaMD) [47]

The concept of Software as a Medical Device (SaMD), as outlined by the International Medical Device Regulators Forum (IMDRF) [17,18], as *"software intended for one or more medical purposes that performs those purposes without being part of a hardware medical device."* .In the Indian context, the Central Drugs Standard Control Organization (CDSCO)[13] adopts a similar interpretation, defining SaMD as software that serves a medical function for humans or animals and achieves its intended purpose through mechanisms other than pharmacological, immunological, or metabolic actions. Instead, its functionality is directed toward achieving clinical outcomes such as diagnosis, monitoring, treatment, or prevention of diseases.

Under Indian regulation, SaMD may be treated either as a standalone digital product or as a component embedded within a hardware-based medical device, provided it contributes to a recognized medical function. These include disease detection, therapy assistance, life support, sterilization processes, or reproductive health applications.

The regulatory inclusion of SaMD was formally established through Notification S.O. 648(E) issued on February 11, 2020, which brought such software under the scope of the Medical Device Rules, 2017**.** Subsequently, in September 2021**,** CDSCO released comprehensive guidance for the risk-based classification of SaMDs, aligned with the IMDRF framework. This system classifies SaMDs into four categories depending on the potential risk posed to patients or users: Class A: Low risk, Class B: Low to moderate risk, Class C: Moderate risk & Class D: High risk.[47]

As of now, India has no dedicated regulatory frameworks for real-world evidence (RWE), special approval pathways, or specific oversight of AI/ML-enabled medical devices, including generative artificial intelligence. [19] Additionally, India does not have a dedicated cyber security law for medical devices. Cyber security concerns are currently addressed under the Information Technology Act, 2000, and its corresponding rules and regulations, which provide general guidance on cyber security and address cybercrime. [19]

4. COMPARATIVE STUDY OF MEDICAL DEVICES REGULATIONS OF SELECTED COUNTRIES

4.1 Medical Devices Regulations of Australia

The Therapeutic Goods Administration (TGA) regulates medical devices under the Therapeutic Goods Act 1989 and the Medical Devices Regulations 2002[20]. Classification follows a seven-tier risk model: Class I, Is (sterile), Im (measuring), IIa, IIb, III, and Active Implantable Medical Device (AIMD)[21]. To obtain market authorization in Australia, all medical devices must be listed in the Australian Register of Therapeutic Goods (ARTG). While Class I devices are eligible for self-certification by the sponsor, higher-risk categories—such as Class Is, Im, IIa, IIb, and III—require a conformity assessment. This assessment must be conducted either by the Therapeutic Goods Administration (TGA) or by an overseas body recognized by the TGA for its conformity assessment capabilities. Compliance with quality management system (QMS) standards, particularly ISO 13485, and certification under the Medical Device Single Audit Program (MDSAP) are commonly accepted benchmarks to demonstrate QMS adherence. Clinical evidence is mandatory for Class IIa and above. The UDI system, known as Australian Unique Device Identification Database (AusUDID), was introduced in 2021, with phased implementation ongoing [22]. The data in the AusUDID links to the relevant inclusion(s) in the Australian Register of Therapeutic Goods (ARTG)[23].Post-market obligations include mandatory adverse event reporting and recall coordination. TGA released SaMD-specific guidance aligned with IMDRF principles, covering AI-based products. The Priority Review Pathway expedites market access for innovative devices.

4.2 Medical Devices Regulations of Canada

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In Canada, medical devices are regulated by Health Canada under the authority of the Food and Drugs Act and the Medical Devices Regulations (SOR/98-282) [24]. Medical devices in Canada are classified into four categories according to their level of risk, from Class I (lowest risk) to Class IV (highest risk). For Class I devices, manufacturers are required to obtain Medical Device Establishment Licence (MDEL) to legally sell their products in the Canadian market while for remaining classes Medical Device Licence (MDL) is required. Quality management relies on ISO 13485, and the Medical Device Single Audit Program (MDSAP) is mandatory for Class II–IV devices [25]. The MDSAP is designed and developed so that a single audit program allows regulatory agencies to efficiently leverage resources, reduce regulatory burden on industry without compromising public health, and promote more aligned and consistent technical requirements [26]. For Class III and Class IV medical devices, the submission of clinical evidence is a regulatory requirement in Canada. While foreign clinical data may be accepted, it must conform to Health Canada's regulatory expectations. The use of international guidelines, such as ISO 14155 (Clinical investigation of medical devices for human subjects), is generally consistent with Canada's standards for clinical trials, ensuring alignment in ethical and scientific principles governing human research. Research Ethics Boards (REBs) play an important role in the oversight of the conduct of investigational testing, for all clinical trials involving medical devices [27]. Canada is piloting a UDI system with full implementation expected by 2026. Post-market surveillance includes mandatory adverse event reporting and active recall management. Health Canada issued draft guidance on SaMDs in 2021 aligned with IMDRF guidelines. Innovation programs are being considered for streamlined access to new technologies.

4.3 Medical Devices Regulations of United States of America (USA)

The FDA's Center for Devices and Radiological Health (CDRH) regulates medical devices under the Federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations [(21 Code of Federal Regulations (CFR) Parts 800–898].[28] Devices are classified into Class I (low), Class II (moderate), and Class III (high risk) [29]. The main premarket approval routes include the 510(k) pathway for substantial equivalence, the De Novo pathway for novel low- to moderate-risk devices, and Premarket Approval (PMA) for high-risk products. [28] The Quality System Regulation (QSR) under 21 CFR 820 outlines Good Manufacturing Practices (GMP), and harmonization with ISO 13485 is underway [30]. In the United States, clinical evidence is mandatory for all Class III medical devices and for a significant number of Class II devices, particularly those that present moderate to high risk or lack a predicate device for substantial equivalence. The Investigational Device Exemption (IDE) pathway, governed by 21 CFR Part 812, facilitates the conduct of clinical studies to support such evidence. Labeling follows requirements in 21 CFR Part 801, and the UDI system is fully operational via the Global Unique Device Identification Database (GUDID) database. It is a publicly accessible database managed by the US FDA that contains information about medical devices that carry UDI. The Medical Device Reporting (MDR) regulation ensures post-market safety monitoring alongside platforms like Med Watch and the Manufacturer and User Facility Device Experience (MAUDE) database [31]. SaMDs and AI/ML-based medical devices are regulated under FDA's Digital Health Innovation Action Plan and specific AI/ML guidance [32]. Innovative medical devices may qualify for expedited regulatory pathways in the United States, such as the Breakthrough Devices Program and the Safer Technologies Program, which are designed to accelerate market access for products addressing unmet medical needs or offering significant safety advantages.

4.4 Medical Devices Regulations of United Kingdom (UK)

The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates devices under the UK Medical Devices Regulations (UK MDR) 2002, as amended post-Brexit [33] Risk classification follows the EU model: Class I, IIa, IIb, and III, including Active Implantable Medical Devices (AIMDs)[33]. Devices are approved through UK Conformity Assessed (UKCA) mark via Approved Bodies, and CE-marked devices are still temporarily accepted.[33] Manufacturers must register devices with MHRA, and ISO 13485 is essential for quality assurance. A UK Responsible Person must be appointed to act on behalf of the manufacturer located outside the UK for fulfilling regulatory obligations within the United Kingdom. UK responsible person is responsible for registering the device with the MHRA.[33] Clinical evidence requirements mirror the EU MDR.

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Post-market surveillance is transitioning under the June 2025 reform, which mandates vigilance reports via the MHRA's Manufacturer's Online Reporting Environment (MORE) portal [34]. It allows for the efficient submission of medical device reports, providing a centralized database that can be analysed and reviewed to identify potential risks and areas for improvement. Patients, healthcare professionals and other device users can report an issue with a medical device to the Yellow Card System. This System safeguards medical devices quality in the UK [35]. The Medical Devices (Post-market Surveillance Requirements) (Amendment) Regulations 2024 introduce notable updates to the UK Medical Devices Regulations 2002 (UK MDR 2002) through the addition of Part 4A, which sets out more rigorous post-market surveillance (PMS) requirements. These updated provisions are applicable to a wide range of devices marketed in UK, including in vitro diagnostic (IVD) devices and active implantable medical devices. While Unique Device Identification (UDI) systems are currently under development, Software as a Medical Device (SaMD) continues to be regulated through interim guidance, with dedicated regulations for artificial intelligence and machine learning (AI/ML) technologies expected as part of the UK's forthcoming regulatory roadmap [36].The Innovative Licensing and Access Pathway (ILAP) provides an accelerated route for breakthrough medical technologies, facilitating earlier patient access and streamlined regulatory engagement.

4.5 Medical Devices Regulations of European Union (EU)

The EU regulates medical devices under Medical Device Regulations (MDR) 2017/745 since 26 May 2021 and In Vitro Diagnostic Devices under In Vitro Diagnostic Devices Regulations 2017/746 (IVDR) since 26 May 2022 [37]. Devices are classified from Class I to III and Active Implantable Medical Device (AIMD) [38]. Conformity assessment and CE marking are mandatory for moderate to high-risk devices, with Notified Bodies conducting third-party evaluations. These high-risk medical devices include: Class III implantable devices and class IIb active devices that are intended to administer or remove medicinal products from the body, Class D in vitro diagnostic medical devices [37] Manufacturers must comply with ISO 13485 and the General Safety and Performance Requirements (GSPRs) outlined in MDR Annex I. Clinical evaluations are mandatory for all medical devices under the EU Medical Device Regulation (MDR), regardless of risk class, and must be documented in a Clinical Evaluation Report (CER). [39] CER presents the results of the clinical evaluation of a medical device. It serves as evidence that the device meets the General Safety and Performance Requirements (GSPRs) set out in Annex I of the MDR. The Unique Device Identification (UDI) system is mandatory and integrated into the European Database on Medical Devices (EUDAMED) database [40]. Post-market requirements include trend reporting, Periodic Safety Update Reports (PSURs), and a centralized vigilance system. Unique Device Identification (UDI) is mandatory and must be submitted to the EUDAMED.[40] SaMDs, including AI/ML tools, are regulated under MDR Annex XVI and follow IMDRF guidelines . While formal fast-track pathways are limited, the MDR includes adaptive mechanisms for legacy and orphan devices. [37][41]

4.6 Medical Devices Regulations of Japan

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW) jointly oversee medical device regulation under the Pharmaceuticals and Medical Devices Act (PMD Act) which came into effect in November 2014 and classified medical devices by risk base concept.[42] The Ministry of Health, Labour and Welfare (MHLW) oversees key administrative duties in Japan, including the issuance of regulatory guidance, making product approval decisions under the Act on securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and determining whether a product falls within the definition of a medical device. The PMDA, in contrast, is tasked with conducting product reviews, risk assessments, and implementing post-market safety measures. Medical devices in Japan are classified into four risk-based categories: Class I (low risk), Class II, Class III, Class IV (high risk). Class I devices can be self-declared by the manufacturer. Class II devices require certification by a Registered Certification Body (RCB). For Class III and Class IV devices, a formal review by the PMDA followed by approval from the MHLW is mandatory [43]. The Quality Management System (QMS) aligns with ISO 13485 standards. Clinical trials are required for Class III/IV devices, with conditional acceptance of foreign data. Post-market surveillance is conducted

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under Good Vigilance Practices (GVP), requiring adverse event reporting and field safety actions[44] Medical Information for Risk Assessment Initiative (MIHARI) is an activity for reinforcement and enhancement of the process and system for collection of safety information and evaluation of medical products, which, enables a drug safety assessment based on medical information data such as claims for medical fees and electronic medical record data that medical institutions input and accumulate for the purpose of daily medical practices. MIHARI was launched in 2009 with the aim of improving the quality of PMDA's post marketing safety measures. [44] PMDA has implemented the Japanese Registry for Mechanically Assisted Circulatory Support (J-MACS) as part of its enhanced post-market safety surveillance initiatives for medical devices. The establishment of this registry supports the enhancement of clinical assessment, therapeutic decision-making, and innovation in technologies used for managing advanced heart failure. In Japan, UDI system and classification of medical devices are based on the Japan Medical Device Nomenclature (JMDN). Additionally, both the Ministry of MHLW and the PMDA have actively participated in the Medical Device Single Audit Program (MDSAP) since June 2015, promoting alignment with global standards for quality system audits. Emerging digital health technologies, including Software as a Medical Device (SaMD) and those incorporating artificial intelligence (AI) or machine learning (ML), are regulated in Japan through a risk-based framework, with recent regulatory initiatives aiming to address the unique characteristics of these evolving technologies. The SAKIGAKE fast-track program supports early access for innovative, high-impact medical technologies.

5. Comparative Table, Key Findings, and Discussion

5.1 Comparative study of Medical Device Regulations of India, USA, UK, EU, Japan, Australia and Canada, was carried out and summary of comparison is given below in table.

Table 7: Summary Table: Medical Device Regulatory Comparison

Parameter	India	USA	UK	EU	Japan	Australia	Canada
Legal basis	Medical Devices Rules, 2017 under D&C Act, 1940	FD&C Act; 21 CFR Parts 800–898	UK MDR 2002, amended post-Brexit	MDR 2017/745 & IVDR 2017/746	Pharmaceutical & Medical Device Act, 2014	Therapeutic Goods Act 1989 and its supporting legislation, the Therapeutic Goods Regulations 2002.	Food and Drugs Act, with detailed provisions outlined in the Medical Devices Regulations (SOR/98-282).
Regulatory Authority	CDSCO	CDRH, FDA	MHRA	National Competent Authorities + Notified Bodies	PMDA (reviews), MHLW (approves)	TGA	Health Canada
Classification (Low to High Risk)	Class A, B, C, D	Class I, II, III	Class I, IIa, IIb, III, AIMD	Class I, IIa, IIb, III, AIMD	Class I, II, III, IV	Class I, Is, Im, IIa, IIb, III, AIMD	Class I, II, III, IV

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Quality System Standard	ISO 13485 recommended (Not mandatory)	Mandatory Quality Management System Regulations (21 CFR 820)QMSR aligned with ISO 13485	Mandatory ISO 13485	Mandatory ISO 13485 + MDR GSPRs	Japan QMS Ordinance (aligned with ISO 13485)	Mandatory ISO 13485; accepts MDSAP	Mandatory MDSAP mandatory (ISO 13485)
Premarket Pathways	MD-3/6 (manufacture), MD-14/15 (import)	510(k), De Novo, PMA	UKCA mark via Approved Bodies	CE Mark via Notified Bodies	Certification (Class II), Approval (Class III/IV)	ARTG registration; mutual recognition	MDL (Class II–IV); MDEL (Class I)
Clinical Evidence	Required for Class C/D; reference countries data accepted	Required for Class III & novel devices	Required for Class IIb/III & innovative devices	CER + trials (Annex XIV, MDR)	Required for Class III/IV; foreign data accepted	Required for high-risk devices	Required for Class III/IV; foreign data accepted
Post-Market Surveillance	Weak; MvPI (Materiovigilance Programme of India)	Strong; MedWatch, MAUDE, recalls	Strong; Vigilance system, field safety notices	Strong; EUDAMED, PSURs, PMS plans	Mandatory; GVP (Good Vigilance Practices)	Mandatory Adverse Event reporting, recalls	Mandatory incident reporting, recalls
Unique Device Identification (UDI) **Implementation**	Phased rollout from 2022	Fully implemented via GUDID	Under development	Implemented in phases; EUDAMED database	Implemented using JMDN and labeling rules	UDI implemented for high-risk devices first	Voluntary pilot (2023); mandatory by 2026
Digital Health/AI/MLSaMD Regulation	No separate Framework	SaMD guidance + AI/ML policies	Interim guidance; digital health reforms expected	MDR Annexure XVI; IMDRF-aligned	Regulated under PMD Act; AI controls evolving	Guidance issued in 2021; IMDRF framework adopted	Draft SaMD guidance (2021); IMDRF-based regulation
Innovations/Fast Track Programme	No clear pathway for innovation or digital health devices	Breakthrough Device Program, De Novo pathway	Innovative Licensing and Access Pathway (ILAP)	Provisions for innovative devices	SAKIGAKE fast-track for innovative devices	Priority Review Scheme	Emerging programs for innovation

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Medical Device Single Audit Program (MDSAP) membership	No	Yes	No	No	Yes	Yes	Yes
International Harmonization	IMDRF member; accepts six reference countries	IMDRF & Global Harmonization Task Force(GHTF) founding member	Post-Brexit divergence; IMDRF alignment	IMDRF member; MDR complies with GHTF	IMDRF member; regional harmonization	IMDRF + MDSAP participant	IMDRF + MDSAP member
Technical Capacity	Limited device-specific experts	Strong technical expertise	Robust technical capacity	Highly trained regulatory experts	Strong technical capacity	Skilled regulatory teams	Strong regulator workforce

5.2 Strengths of Indian Medical Device Regulations

(1) Establishment of Dedicated Medical Device Rules (2017) [15]

With the implementation of the Medical Devices Rules (MDR) in 2017[15] **,** India took a significant step toward distinguishing medical devices from pharmaceutical products. This rule creates dedicated guidelines suitable for medical devices regulatory process and enhances transparency. This shift helped move oversight away from the outdated drug-based framework and allowed for more targeted regulation of device-specific features.

(2) Adoption of Risk-Based Classification [15]

India adopted a risk-based classification system for medical devices and in vitro diagnostic (IVD) devices, categorizing them into Classes A through D. [15] This aligns with internationally recognized practices used by major regulators like US FDA, European Medicines Agency, Health Canada, and Australia's Therapeutic Goods Administration (TGA) ensuring that higher-risk devices are subject to more stringent oversight and thereby enhancing patient safety.

(3) Comprehensive Guidelines for Market Authorization [15]

The Medical Devices Rules (MDR), 2017, establishes a comprehensive regulatory framework governing the import, manufacture, clinical investigation, sale, and distribution of medical devices in India. [15]It requires manufacturers and importers to be registered and licenced, thereby promoting regulatory transparency and accountability.

(4) Government Support through Policy and Infrastructure [4]

The Government of India has introduced multiple initiatives, such as the development of Medical Device Parks and the implementation of Production-Linked Incentive (PLI) schemes, to enhance domestic manufacturing capabilities and reduce dependency on imports. [4] These efforts are in line with the 'Make in India' initiative [1] and aim to position, India as a key global hub for the manufacturing of medical devices.

(5) Encouragement of International Quality Standards [15]

Although not compulsory for all devices, MDR encourages ISO 13485:2016 certification for quality management. This encourages manufacturers to meet global quality standards and improves the credibility of Indian-made devices in international markets.

(6) Expansion of Regulatory Coverage over Time [45]

Starting from a limited number of notified devices, India has progressively brought all medical devices under regulation. This phased expansion helps ensure that both high-risk and widely used general devices such as

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cardiac stents, orthopedic implants, and diagnostic instruments meet uniform safety and efficacy standards.

(7) Launch of the Materiovigilance Programme of India (MvPI)[16]

India has launched the Materiovigilance Programme of India (MvPI) to enhance post-market surveillance and uphold the ongoing safety of medical devices. Though still in its early stages, the program helps collect data on adverse events and supports long-term safety monitoring of devices in real-world use.

5.3 Weaknesses of Indian Medical Device Regulations

(1) Continued Reliance on the Drugs and Cosmetics Act [46]

Even with the MDR, medical devices are still governed under the broader Drugs and Cosmetics Act, 1940. —an outdated statute originally intended for pharmaceuticals. This Act, initially designed for drugs, lacks the specificity needed for the regulation of technologically advanced medical devices. This leads to legal ambiguity and limited regulatory adaptability.

(2) Limited Clinical Data Requirements [41]

In contrast to developed markets where comprehensive clinical trials are standard, India mandates such studies only for high-risk (Class C and D) devices. This gap raises concerns about the safety and efficacy evaluations for lower-risk device categories.

(3) Insufficient Regulatory Capacity [46]

The Central Drugs Standard Control Organization (CDSCO) faces a shortage of trained staff with device-specific expertise, particularly in emerging areas like AI, ML, and implants. This shortage results in slow approvals and inconsistent evaluations, impacting both innovation and safety monitoring.

(4) Weak Post-Market Surveillance (PMS) and adverse event reporting system [41]

The Materiovigilance Programme of India (MvPI) currently relies heavily on voluntary reporting, and enforcement mechanisms are underdeveloped. There is no mandatory reporting requirement or real-time risk communication infrastructure comparable to those in developed countries. India still does not have a nationwide, real-time system like the FDA's MedWatch or Europe's EUDAMED, limiting recall effectiveness and patient protection. [41]

(5) Voluntary Quality Management System (QMS) Compliance

Compliance with ISO 13485 is encouraged but not uniformly enforced, particularly for Class A and B devices. This weakens the quality assurance framework, particularly for Class B and C devices. Countries like Australia and Canada mandate QMS adherence for all classes, ensuring a more consistent manufacturing standard.

(6) No Specific Framework for Digital Health and SaMD [47]

India does not have a distinct framework for regulating Software as a Medical Device (SaMD), AI/ML-enabled devices, or digital health platforms. The lack of clarity could delay innovation in a rapidly evolving field and places India behind countries that have adopted IMDRF-based SaMD guidance.

(7) Limited Participation in Global Harmonization Initiatives [48]

India is not a part of initiatives like the Medical Device Single Audit Program (MDSAP) and has only partial engagement with IMDRF frameworks. This lack of harmonization creates trade barriers and undermines the global credibility of Indian regulatory decisions.

(8) No Fully Implemented UDI System [15]

A mandatory UDI system is still under development in India. The absence of UDI makes it difficult to track devices through their lifecycle, hinders effective device recalls, or ensures traceability across the supply chain.

(9) Lack of Publicly Accessible Regulatory Information

Unlike the US FDA's MAUDE database or the EU's EUDAMED[40], India does not yet offer a comprehensive public platform where stakeholders can view approved products, adverse events, or recalls. This reduces transparency and weakens public and professional trust.

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5.4 Recommendations to Align India's Medical Device Regulations with Developed Countries

Table 8: Recommendations to strengthen Medical Devices regulations of India

Recommended Parameter	Best Practice (Global Reference)	Policy Recommendation for India	Benefit to India after Implementation
Enact a Comprehensive and Standalone Medical Device Law	USA (FDA), EU (MDR/IVDR), UK (MHRA), Canada, Australia (TGA) have separate device laws	Draft and implement a Medical Device Act distinct from D&C Act; include classification, clinical trials, PMS, recalls, SaMD & AI	Ensures legal clarity, reduces regulatory overlap, improves global market confidence
Strengthen Risk-Based Classification & Regulatory Pathways	Four-tier risk classification (Class I–IV); IMDRF-aligned in EU, USA, Canada, Australia	Harmonize classification with IMDRF; define clear approval pathways for SaMD, AI/ML, 3D-printed, and combination products	Balances innovation with patient safety; eases global alignment
Implement Mandatory QMS & ISO 13485 Compliance	ISO 13485 mandatory in Canada, EU, Australia; aligned with FDA's QMSR	Make ISO 13485 mandatory for Class B–D; regular audits by CDSCO/state bodies; strengthen third-party inspections	Improves device quality, enables exports, enhances trust
Build a Robust Post-Market Surveillance (PMS)	FDA (MAUDE), EU (EUDAMED), Canada (Mandatory PMS), Australia (MDIR)	Create digital National Device Vigilance System; make PMS reporting mandatory; public database on devices & events	Increases safety, enables early issue detection, builds public trust
Introduce Unique Device Identification (UDI)	UDI implemented in USA, EU, Australia, Canada, UK	Adopt global UDI system for all devices; mandatory for traceability and recalls	Enhances safety, recall efficiency, and supply chain transparency
Mandate Clinical Data & Real-World Evidence (RWE)	Clinical data and RWE mandated in USA (PMA), EU (CER), Australia	Require clinical trials for Class B–D similar to the EU MDR (2017/745) and FDA's PMA pathway; adopt ISO 14155 for clinical trials; incentivize India-specific trials; encourage Real world evidence (RWE)	Improves regulatory decisions and international acceptance
Develop Fast-Track Pathways for Breakthrough and Innovative Devices	FDA's Breakthrough Device Program and UK's Innovative Licensing and Access Pathway (ILAP), Japan's SAKIGAKE program**.**	Create a fast-track approval for breakthrough, indigenous, digital technologies; provide regulatory support to MSMEs/startups	Boosts innovation, accelerates AI/ML-driven medical devices and digital health technologies.

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Regulate Digital Health, Software as a Medical Device (SaMD) & AI/ML Devices	SaMD guidance in FDA, EU, Australia; IMDRF-aligned	Draft clear guidelines for SaMD, AI/ML; ensure cybersecurity and data privacy	Enables innovation in SaMD, AI/ML driven devices, provides clarity to developers, aligns with global norms
Foster International Harmonization & Mutual Recognition Agreements (MRAs)	Mutual recognition of certifications like CE Marking & MDSAP in Canada, Australia, USA	Join MDSAP, engage in MRAs with US, EU, UK, etc.; participate in IMDRF actively	Improves export readiness, encourages FDI, enables mutual acceptance
Recommended Parameter	**Best Practice (Global Reference)**	**Policy Recommendation for India**	**Benefit to India after Implementation**
Continuous Regulatory Updates & Capacity Building	Regular updates by FDA, EU, Health Canada	Update rules every 3–5 years; recruit technical experts of device-specific experts, biomedical engineers, and AI specialists in CDSCO; upskill state regulators. Collaborate with global regulatory experts for capacity-building initiatives.	Makes Indian system adaptive, modern, and globally benchmarked
Build Medical Device Parks & strengthen Academia-Industry Collaboration	MedTech clusters in Ireland, USA	Strengthen medical device parks; promote academic partnerships for R&D, testing, innovation	Reduces import dependency, promotes domestic manufacturing

6. Conclusion:

India has made significant strides in establishing a comprehensive regulatory framework for medical devices through the Medical Devices Rules (MDR), 2017. The introduction of risk-based classification, licensing mechanisms, and alignment with ISO 13485 indicates a positive trajectory toward international harmonization. However, compared to mature regulators in the USA, EU, UK, Canada, Australia, and Japan, India still lags in key areas such as post-market surveillance, digital health governance, innovation pathways, and real-world evidence integration. To position itself as a global MedTech leader and realize the ambitions of the "Make in India" initiative, India must align with international best practices in medical device evaluation, clinical evidence generation, and post-market surveillance. Key priorities should include the strengthening of the Materiovigilance Programme of India (MvPI), the nationwide implementation of a Unique Device Identification (UDI) system, the introduction of expedited approval pathways for innovative technologies, and the establishment of clear regulatory frameworks for Software as a Medical Device (SaMD).

Harmonization with global standards, alongside strategic initiatives such as the Production Linked Incentive (PLI) scheme, the development of MedTech parks, and active

participation in the International Medical Device Regulators Forum (IMDRF), provides a critical pathway toward regulatory convergence. Addressing current regulatory and infrastructural gaps will enhance foreign investment, stimulate domestic innovation, and ensure the availability of high-quality, safe, and effective medical devices for both national and international markets.

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