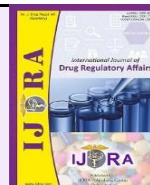




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Review Article

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Comparative Analysis of Regulatory Approval Processes for Medical Devices in India and the European Union

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Abstract

The regulatory approval framework for medical devices is essential to ensure safety, performance, and quality before market entry. This article presents a comparative analysis of the approval processes in India and the European Union (EU), highlighting structural and procedural differences. In India, devices are regulated under the Medical Devices Rules, 2017 by the Central Drugs Standard Control Organization (CDSCO), using a risk-based classification system with defined requirements for licensing, clinical investigation, and post-market surveillance. In contrast, the EU Medical Device Regulation (EU) 2017/745 (MDR) establishes a more comprehensive framework involving notified bodies, conformity assessment, CE marking, clinical evaluation, and stringent vigilance mechanisms. This comparison supports strategic regulatory planning and identifies opportunities for harmonization in global medical device regulation.

Conclusion: This comparative analysis of the regulatory approval processes for medical devices in India and the European Union demonstrates that both jurisdictions are grounded in risk-based regulatory philosophy, yet differ substantially in the depth, structure, and lifecycle integration of regulatory oversight.

Keywords: Medical devices, approval processes, EMA, CDSCO, guidelines, Medical device licensing

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1. Introduction

Medical devices constitute a cornerstone of contemporary healthcare systems, enabling disease prevention, diagnosis, monitoring, treatment, rehabilitation, and life support across diverse clinical settings. The sector encompasses a wide spectrum of products, ranging from low-risk consumables such as surgical dressings and thermometers to high-risk implantable devices, cardiovascular prostheses, advanced diagnostic platforms, and software-driven medical technologies. Unlike medicinal products, medical devices generally achieve their intended purpose through physical, mechanical, or technological mechanisms rather than pharmacological, immunological, or metabolic action, thereby necessitating distinct regulatory evaluation frameworks. (1)

The legal definition of a medical device varies slightly across jurisdictions but remains conceptually aligned. Under the Medical Devices Rules, 2017, implemented by the Central Drugs Standard Control Organization (CDSCO), a medical device includes any instrument, apparatus, appliance, implant, material, or software intended for diagnosis, prevention, monitoring, treatment,

or alleviation of disease; support of anatomical or physiological functions; life support; or disinfection of medical devices. (2) Similarly, Regulation (EU) 2017/745 on medical devices (MDR) defines medical devices as instruments, apparatus, appliances, software, implants, reagents, or materials intended by the manufacturer for specific medical purposes, including diagnosis, monitoring, prediction, prognosis, treatment, or alleviation of disease. (3) Despite definitional similarities, regulatory interpretation, implementation rigor, and oversight structures differ substantially between regions.

The globalization of medical device manufacturing, expansion of cross-border trade, and increasing technological complexity have intensified the need for robust and harmonized regulatory oversight. Regulatory systems must balance two competing objectives: ensuring patient safety and facilitating timely access to innovative technologies. Inadequate regulation may expose populations to unsafe devices, whereas excessive procedural burden may delay innovation and increase healthcare costs. Consequently, regulatory science has emerged as a critical discipline aimed at optimizing risk-

based evaluation, conformity assessment, and lifecycle monitoring of medical devices. (4, 5)

India represents one of the fastest-growing medical device markets globally, valued at approximately USD 12 billion in 2024, with substantial expansion in domestic manufacturing and foreign investment. (6) Historically regulated under the Drugs and Cosmetics Act, medical devices in India are now governed by the Medical Devices Rules, 2017, which introduced a structured risk-based classification system comprising Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk), and Class D (high risk) categories. Regulatory control intensifies proportionally with risk class, with licensing oversight shared between the CDSCO and State Licensing Authorities (SLAs). Compliance with ISO 13485 quality management systems is mandatory, (7) and in certain circumstances, prior approvals from established regulatory authorities such as the United States Food and Drug Administration (US FDA) or European authorities may facilitate market authorization. While recent reforms have strengthened regulatory clarity and expanded device coverage, challenges persist in areas such as post-market surveillance robustness, regulatory capacity, and alignment with international best practices. (8)

In contrast, the European Union operates under a mature and highly structured regulatory regime formalized through Regulation (EU) 2017/745 (MDR), which replaced the earlier Medical Device Directives to address regulatory gaps and enhance patient safety. The MDR establishes a comprehensive lifecycle-based framework emphasizing clinical evaluation, transparency, traceability through Unique Device Identification (UDI), and reinforced post-market surveillance. Devices are categorized into Class I, IIa, IIb, and III based on risk, with higher-risk devices subject to rigorous conformity assessment by designated Notified Bodies. Manufacturers must demonstrate compliance with General Safety and Performance Requirements (GSPRs), submit extensive technical documentation, conduct clinical investigations where necessary, and implement post-market clinical follow-up (PMCF) systems. Upon successful assessment, CE marking permits free circulation within EU member states. The EU medical device market, valued at approximately €142 billion in 2024, reflects both the scale and regulatory sophistication of the region. (9)

Although both India and the European Union adopt risk-based classification principles consistent with international harmonization efforts such as those promoted by the International Medical Device Regulators Forum (IMDRF) notable differences remain in regulatory architecture, documentation rigor, clinical evidence expectations, conformity assessment pathways, approval timelines, and post-market enforcement strategies. India's framework demonstrates increasing regulatory consolidation but remains comparatively streamlined in certain approval pathways and more flexible regarding foreign clinical data acceptance. Conversely, the EU MDR imposes extensive local validation requirements, structured vigilance mechanisms, and periodic safety updates, resulting in greater procedural complexity and compliance burden. (10)

Given the strategic importance of both jurisdictions in the global medical device ecosystem, a systematic comparative evaluation of their regulatory approval processes is essential. Such analysis informs manufacturers seeking multi-jurisdictional market access, supports policymakers aiming to strengthen domestic regulatory capacity, and contributes to the evolving discourse on global regulatory harmonization.

This study therefore undertakes a comprehensive comparative analysis of the regulatory approval processes for medical devices in India and the European Union. It examines governing authorities, classification systems, conformity assessment procedures, clinical evaluation standards, approval timelines, market scale, and post-market surveillance mechanisms. By identifying structural divergences and areas of convergence, the article contributes to regulatory science scholarship and highlights opportunities for strategic alignment in global medical device governance.

2. Regulatory approval process for medical devices in India

The regulatory approval process for medical devices in India is governed by the Medical Devices Rules, 2017 (as amended), notified under the Drugs and Cosmetics Act, 1940. These rules marked a significant transition from the earlier fragmented regulatory approach toward a structured, risk-based framework aligned with global regulatory principles promoted by the International Medical Device Regulators Forum (IMDRF). The Indian system adopts a proportional regulatory model in which the degree of pre-market scrutiny, documentation requirements, and oversight intensity increase in accordance with the device's risk classification.

The approval process formally begins with classification of the device into one of four categories—Class A (low risk), Class B (low to moderate risk), Class C (moderate to high risk), and Class D (high risk). This classification determines the competent licensing authority and the conformity assessment pathway as prescribed under the Medical Devices Rules, 2017. As illustrated in the regulatory flow framework, Class A and Class B devices follow a state-level licensing route, whereas Class C and Class D devices are evaluated centrally by the Central Licensing Authority (CLA) under the Central Drugs Standard Control Organization (CDSCO). (11)

For Class A and Class B devices, manufacturers are required to submit an application in Form MD-3 to the State Licensing Authority (SLA). The application dossier includes a device master file, plant master file, quality management system documentation compliant with ISO 13485, and evidence demonstrating conformity with the Essential Principles of Safety and Performance. In the case of Class A devices, regulatory review is primarily documentation-based, reflecting their low-risk profile under the proportional regulatory framework. A manufacturing site audit may be conducted post-licensure within 120 days, indicating a relatively facilitative approach intended to reduce regulatory burden while maintaining oversight.

For Class B devices, however, the process incorporates an additional layer of conformity assessment. A Notified Body accredited by the National Accreditation Board for Certification Bodies conducts an audit of the manufacturing site. The audit report is submitted to the SLA, typically within 30 days, following which the authority completes its review, generally within 90 days. This intermediate oversight mechanism reflects India's attempt to introduce structured third-party assessment while retaining state-level licensing control. (12)

The approval pathway becomes significantly more stringent for Class C and Class D devices. Applications are submitted in Form MD-7 to the CLA. In these cases, technical documentation undergoes detailed scrutiny, including evaluation of risk management reports, clinical evidence, and quality system compliance. An inspection is conducted by a Medical Device Officer or designated inspection team as authorized under the Rules. The inspection findings are reviewed centrally, and additional clarifications or corrective actions may be requested. Although initial scrutiny timelines are often indicated as approximately 45 days, the total approval duration may extend depending on the complexity of clinical data and manufacturing arrangements. High-risk devices are therefore subject to a more centralized and technically intensive review process, reflecting the potential consequences of device failure.

The decision-making stage, depicted in the flow sequence as the "review" node, represents the regulatory authority's evaluation of documentation and audit findings. Where compliance with statutory requirements is demonstrated, the authority grants a manufacturing license or registration certificate. In cases of deficiencies, applicants must address observations before final approval. Notably, once granted, licenses are valid in perpetuity, subject to payment of retention fees every five years and continued regulatory compliance as per the amended provisions of the Medical Devices Rules, 2017.

Post-market obligations form an integral component of the Indian framework, although they remain comparatively less mature than those in more stringent jurisdictions. Manufacturers are required to participate in the Materiovigilance Programme of India (MvPI), report adverse events, maintain distribution records, and implement corrective and preventive actions (CAPA). The Materiovigilance Programme operates under the Indian Pharmacopoeia Commission and aims to monitor adverse events associated with medical devices marketed in India. While the regulatory structure emphasizes lifecycle oversight, enforcement mechanisms and digital surveillance infrastructure continue to evolve. (13)

From an analytical perspective, the Indian approval system reflects a hybrid regulatory architecture. It combines centralized oversight for high-risk devices with decentralized state-level control for lower-risk categories. The model attempts to balance administrative efficiency and patient safety within the context of a rapidly expanding domestic market. However, reliance on foreign clinical approvals in certain cases, variable state-level implementation capacity, and developing post-market

surveillance systems indicate areas for further strengthening.

Overall, the Indian regulatory approval process demonstrates progressive alignment with international risk-based regulatory norms while retaining contextual flexibility suited to domestic industrial and healthcare realities. Its tiered flow from classification to application submission, audit, centralized or state-level review, and post-market monitoring illustrates an evolving lifecycle-based regulatory philosophy that continues to mature in response to global harmonization efforts.

3. Regulatory approval process for medical devices in European Union

The European Union (EU) regulates medical devices through a harmonized, lifecycle-based framework primarily established by Regulation (EU) 2017/745 on medical devices (MDR). The MDR replaced the earlier directives (MDD/AIMDD) to strengthen clinical evidence requirements, increase transparency, enhance traceability, and reinforce post-market vigilance following safety concerns observed under the previous regime. Unlike systems in which a single central regulator grants market authorization, the EU model is built around manufacturer responsibility, independent third-party conformity assessment (for most devices), and oversight by Competent Authorities within Member States. The outcome of successful regulatory compliance is CE marking, which enables legal placement of a device on the EU market and, in principle, free movement across Member States. (14)

The approval pathway begins with classification of the device according to MDR risk rules. Devices are categorized as Class I, IIa, IIb, or III, with increasing regulatory obligations as risk rises. This risk classification does not merely label the product; it determines whether conformity assessment can be self-declared (limited scenarios) or whether a Notified Body must independently assess compliance. In practice, the MDR substantially reduced the scope of "self-certification" by expanding categories requiring Notified Body involvement and by tightening rules for borderline, reusable surgical instruments, and certain software-driven devices. (15)

A defining feature of the EU system is that market access is granted when a manufacturer demonstrates conformity with the General Safety and Performance Requirements (GSPRs) set out in Annex I of the MDR. Conformity is evidenced through a structured technical and quality framework. Manufacturers must implement a Quality Management System (QMS) across the product lifecycle; ISO 13485 is widely used as the principal QMS standard for medical devices and is commonly expected in practice, particularly for devices that require Notified Body review.

The "technical file" is not a single document but a structured dossier comprising, among other elements, device description and specification, design and manufacturing information, benefit-risk justification, verification and validation data, labeling/IFU, and a complete demonstration of GSPR conformity (Annex II). In addition, the MDR requires an explicit post-market surveillance (PMS) plan and related lifecycle

documentation (Annex III), reflecting the EU's shift from a pre-market-only mindset toward continuous performance monitoring. (16)

Risk management is another pillar: manufacturers are expected to apply a systematic risk management process throughout the lifecycle, commonly aligned with ISO 14971, to identify hazards, estimate and evaluate associated risks, and implement controls while ensuring that residual risks remain acceptable relative to clinical benefits. The MDR embeds this logic by requiring ongoing benefit–risk acceptability supported by evidence, not only at initial certification but also during post-market follow-up.

The MDR significantly raises expectations for clinical evidence, especially for higher-risk devices. Manufacturers must conduct and document a clinical evaluation that demonstrates conformity with relevant GSPRs, based on clinical data such as clinical investigations, scientific literature, and—where justified—equivalence data. The requirement is not purely procedural: the MDR expects that clinical evidence is sufficient in quality and quantity to substantiate performance claims and safety for the intended patient population and clinical use conditions. For devices where, existing clinical data are insufficient, clinical investigations are required, generally aligned with internationally recognized good clinical practice for devices (e.g., ISO 14155) and subject to ethics and regulatory controls within Member States. A further MDR escalation is the requirement for Post-Market Clinical Follow-up (PMCF) as part of the clinical evaluation lifecycle. PMCF is intended to proactively update clinical evidence, identify emerging risks, and confirm safety and performance in real-world use, particularly important for Class IIb and Class III devices.

The route to approval under the MDR depends on class and device type. The EU model uses several conformity assessment procedures (e.g., Annex IX, X, XI), which broadly combine QMS assessment with product technical documentation review and, where applicable, product verification. For most Class IIa, IIb, and III devices, and for specific Class I subsets (notably reusable surgical instruments), manufacturers must undergo assessment by a Notified Body, an independent organization designated and supervised by Member State Competent Authorities for MDR tasks. Notified Bodies review the QMS, audit manufacturing sites, examine technical documentation, and may perform sampling-based checks across device families. These audits can include scheduled surveillance audits and, under regulatory expectations, the potential for unannounced or short-notice assessments as part of ongoing oversight.

For the highest-risk products, the MDR adds additional controls. Class III implantables and certain Class IIb active devices may be subject to additional scrutiny mechanisms, including structured documentation depth and, in defined circumstances, consultation or review pathways involving expert-level assessment structures. The goal is to reduce variability in decision-making and to increase confidence that high-risk devices receive robust and consistent evaluation.

When conformity is demonstrated, the Notified Body issues relevant certificates (e.g., QMS certificate and/or EU technical documentation assessment certificate, depending on the route). The manufacturer then draws up the EU Declaration of Conformity and affixes the CE marking (with the Notified Body identification number where applicable). The device may then be placed on the EU market subject to other MDR obligations, including economic operator responsibilities and registration requirements.

A major MDR innovation is strengthened traceability through Unique Device Identification (UDI) and expanded registration/data transparency through EU information systems, including EUDAMED functions (implemented progressively). UDI supports supply chain traceability, recall effectiveness, and post-market signal detection. The MDR also introduces enhanced public-facing clinical transparency tools for certain device classes, such as the Summary of Safety and Clinical Performance (SSCP) for implantable and Class III devices.

The MDR explicitly defines obligations for manufacturers, authorized representatives, importers, and distributors. For non-EU manufacturers, appointment of an EU Authorized Representative is mandatory; this entity assumes defined compliance responsibilities and serves as a key legal interface within the EU. Importers and distributors must verify that CE marking, labeling, UDI obligations, and documentation availability are satisfied before making devices available and must participate in complaint handling, corrective actions, and traceability. This “shared accountability” design aims to reduce regulatory blind spots across complex international supply chains.

The EU system is explicitly lifecycle-based. After market entry, manufacturers must operate PMS systems that continuously gather and analyze real-world performance and safety data. Reporting obligations scale with risk. For example, manufacturers of higher-risk devices must prepare Periodic Safety Update Reports (PSURs), which synthesize PMS findings and benefit–risk conclusions on a recurring basis; these are reviewed within the regulatory ecosystem and support ongoing conformity assessment activities. Vigilance requirements mandate timely reporting of serious incidents and field safety corrective actions, enabling coordinated regulatory responses across Member States.

Notified Body surveillance, certificate renewals, and continued QMS compliance collectively function as a “moving approval,” where continued market access depends on continuous evidence generation and system performance rather than a one-time premarket decision.

From a regulatory science viewpoint, the MDR approval pathway is best understood as a structured demonstration of conformity with GSPRs supported by (i) robust QMS implementation, (ii) comprehensive technical documentation, (iii) strengthened clinical evaluation and PMCF and (iv) mandatory post-market surveillance with enforceable vigilance and traceability. The reliance on Notified Bodies introduces specialized third-party review capacity, but also contributes to variability in timelines and increased compliance costs for manufacturers, particularly under the more stringent MDR evidentiary expectations.

Overall, the EU approval process emphasizes precautionary, evidence-driven governance with

continuous lifecycle monitoring, especially for higher-risk devices. (17)

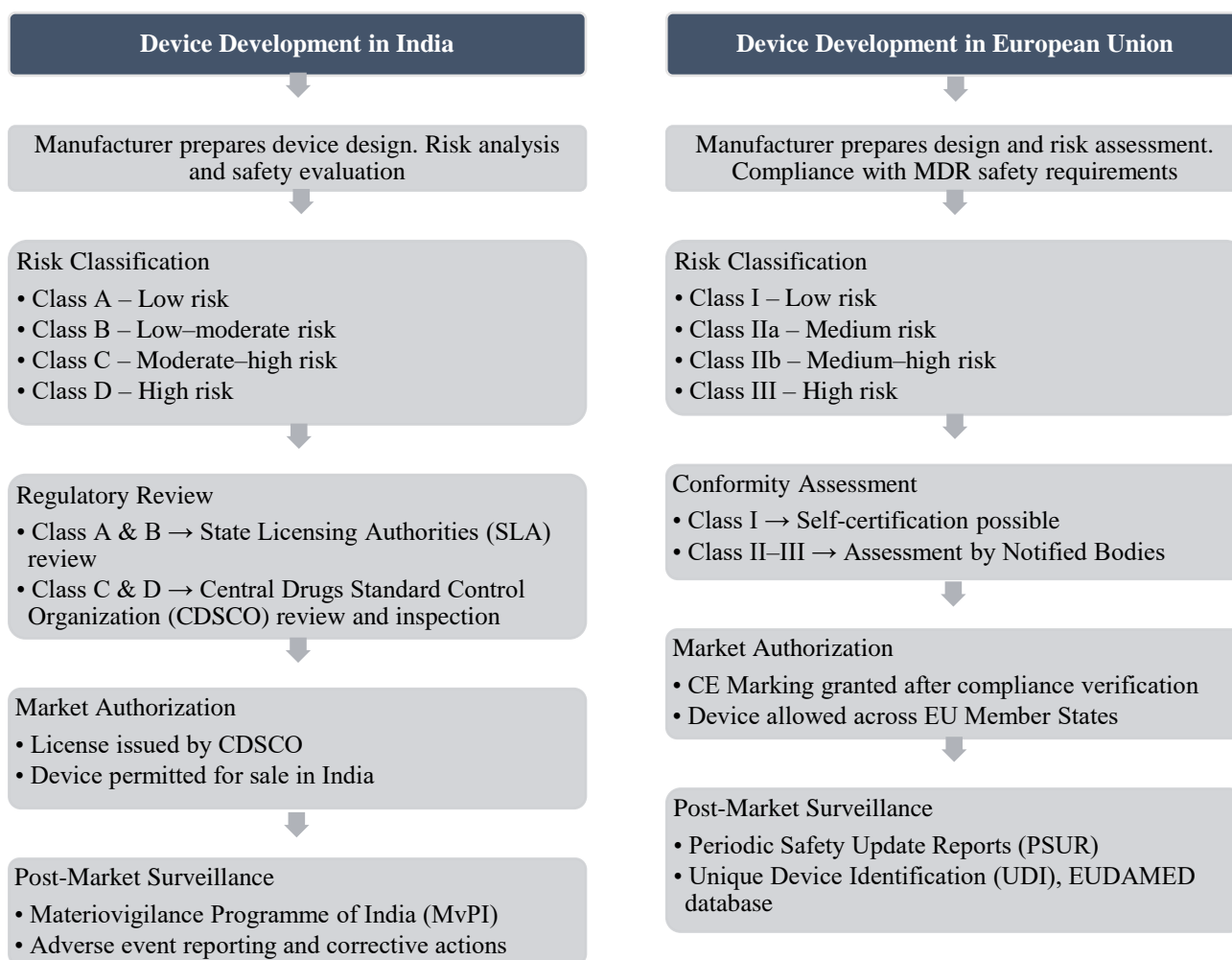


Figure 1. Regulatory approval framework for medical devices in India Vs. European Union

4. Methodology

This study employed a qualitative comparative regulatory analysis design. Primary sources included statutory regulations such as the Medical Devices Rules, 2017 (India) and Regulation (EU) 2017/745 (MDR). Supplementary materials included official guidance documents, international standards (ISO 13485, ISO 14971), policy briefs, and peer-reviewed academic literature.

A structured comparative framework was developed to evaluate five core parameters:

- Regulatory governance structure
- Risk-based classification systems
- Conformity assessment and clinical evidence requirements
- Approval timelines and market access pathways
- Post-market surveillance and vigilance mechanisms

Each parameter was analyzed for procedural architecture, regulatory intensity, and lifecycle oversight integration. The analysis focused on identifying structural similarities, divergences, and implications for multi-jurisdictional regulatory strategy. This methodology enables systematic comparison without reliance on empirical clinical datasets, as the objective of the study is regulatory framework evaluation rather than product-level outcome assessment.

5. Discussion

The comparative evaluation of regulatory approval processes in India and the European Union reveals both structural convergence in risk-based philosophy and significant divergence in procedural rigor, evidentiary standards, and lifecycle governance mechanisms.

5.1 Regulatory governance architecture

The Indian regulatory framework demonstrates a tiered administrative structure combining centralized oversight with delegated state-level implementation. Under the Medical Devices Rules, 2017, lower-risk devices (Class A and B) are primarily regulated by State Licensing Authorities (SLAs), while higher-risk devices (Class C and

D) fall under the jurisdiction of the Central Licensing Authority (CLA) operating through the Central Drugs Standard Control Organization (CDSCO). This division is designed to distribute regulatory workload proportionate to device risk and administrative capacity. In contrast, the European Union operates under a harmonized legislative framework (Regulation (EU) 2017/745) that is directly applicable across Member States. Although the MDR establishes uniform legal requirements, conformity assessment activities are performed by designated Notified Bodies. These entities function under supervision by national Competent Authorities but apply standardized regulatory criteria across the Union. Consequently, while governance is decentralized in implementation, regulatory expectations are highly harmonized.

The analysis indicates that India's model prioritizes administrative feasibility and scalability in a rapidly expanding market, whereas the EU framework prioritizes uniformity, regulatory specialization, and technical independence in assessment procedures.

5.2 Risk classification and regulatory intensity

Both jurisdictions adopt proportional risk-based classification aligned with international regulatory norms. However, differences emerge in the granularity and regulatory consequences of classification. In India, devices are categorized into four classes (A–D), with regulatory oversight intensifying progressively. Class A devices generally undergo documentation-based review with limited pre-licensure inspection. Class B devices require audit by an accredited Notified Body. For Class C and D devices, centralized scrutiny includes detailed technical dossier review and inspection by designated officers. Under the EU MDR, devices are classified into Class I, IIa, IIb, and III based on detailed classification rules covering invasiveness, duration of contact, energy transmission, and software functionality. The regulatory implications of classification are more stringent. Even certain subclasses of Class I devices (e.g., reusable surgical instruments) require Notified Body involvement, a shift introduced by the MDR to reduce risks associated with self-certification.

The findings indicate that although both systems apply proportional regulation, the EU framework imposes broader mandatory third-party assessment, thereby reducing reliance on manufacturer self-declaration compared to the Indian pathway for lower-risk categories.

5.3 Conformity assessment and technical documentation

In India, conformity assessment for lower-risk devices primarily involves review of documentation and quality management system certification (ISO 13485). For moderate- and high-risk devices, inspection reports and technical documentation are evaluated by regulatory authorities. Acceptance of prior foreign regulatory approvals or clinical evidence may expedite review in specific cases. In the EU, conformity assessment under the MDR is structured around comprehensive evaluation of General Safety and Performance Requirements (GSPRs). Manufacturers must maintain extensive technical documentation, including design verification, validation data, benefit–risk analysis, and clinical evaluation reports.

Notified Bodies conduct systematic audits of both the QMS and product-specific technical files. The MDR also integrates surveillance audits and periodic reassessment, embedding continuous oversight into certification validity. The analysis demonstrates that EU conformity assessment operates as a lifecycle-integrated evaluation system, whereas the Indian system remains more focused on pre-market documentation and initial licensing.

5.4 Clinical evaluation and evidence requirements

India permits reliance on published literature, prior foreign approvals, and, where necessary, local clinical investigation data. Although this approach facilitates faster market access, particularly for imported technologies, it may limit population-specific data generation. Under the EU MDR, clinical evaluation is mandatory for all device classes, with increased depth for higher-risk categories. The regulation requires demonstration of clinical safety and performance based on clinical investigations or scientifically justified equivalence data. Post-Market Clinical Follow-up (PMCF) is obligatory for most moderate- and high-risk devices, reinforcing continuous evidence generation. The results therefore suggest that the EU system places greater emphasis on structured, ongoing clinical validation, while India's framework allows greater flexibility in the use of pre-existing global data.

5.5 Approval timelines and administrative burden

In India, licensing timelines for Class A and B devices generally range between six to nine months, subject to completeness of documentation and inspection scheduling. Centralized approval for Class C and D devices may require additional time depending on technical complexity and clarification cycles. In the EU, MDR implementation has lengthened approval timelines, particularly due to limited Notified Body capacity and expanded documentation requirements. High-risk devices may require one to two years for certification under MDR standards.

This comparative finding reflects a trade-off between regulatory thoroughness and market access speed, with the EU emphasizing precautionary rigor and India offering relatively expedited pathways for lower-risk devices.

5.6 Post-market surveillance and vigilance systems

India's Materiovigilance Programme of India (MvPI) facilitates adverse event reporting and safety monitoring; however, enforcement and centralized digital traceability systems remain under progressive development. Reporting obligations exist but lack the structured periodic safety update reporting seen in advanced jurisdictions. The EU MDR mandates comprehensive post-market surveillance plans, periodic safety update reports (PSURs) for higher-risk devices, structured vigilance reporting, and implementation of Unique Device Identification (UDI) for enhanced traceability. The system is designed to proactively identify safety signals and coordinate cross-border corrective actions.

The results indicate that the EU operates a more proactive and data-driven lifecycle monitoring model, whereas India's system is evolving toward stronger integration of post-market oversight mechanisms.

5.7 Market scale and regulatory capacity implications

Economic context also influences regulatory architecture. The EU medical device market, valued at approximately €142 billion in 2024, supports a mature regulatory ecosystem with specialized conformity assessment

infrastructure. India's market, estimated at approximately USD 12 billion, is rapidly expanding but continues to build institutional regulatory capacity. This disparity partly explains differences in technical scrutiny depth, availability of third-party assessment bodies, and surveillance infrastructure sophistication. (18)

Table 1. India vs. EU Medical Device Regulatory Frameworks

Parameter	India (Medical Devices Rules, 2017)	European Union (MDR 2017/745)
Regulatory Authority	Central Drugs Standard Control Organization (CDSCO) with State Licensing Authorities (SLAs) for lower-risk devices	Decentralized system: Notified Bodies conduct conformity assessments under supervision of national Competent Authorities
Risk Classification	Class A (low), Class B (low-moderate), Class C (moderate-high), Class D (high)	Class I, IIa, IIb, III with detailed rules based on invasiveness, duration, software, etc.
Approval Pathway	Class A & B: SLA review (documentation + audits for Class B). Class C & D: Central Licensing Authority review with inspections	Class I (some self-certification), IIa/IIb/III: mandatory Notified Body assessment; conformity procedures via Annex IX–XI
Technical Documentation	Device Master File, Plant Master File, ISO 13485 QMS compliance, Essential Principles of Safety & Performance	Comprehensive Technical File: device description, design/manufacturing data, benefit–risk analysis, GSPR conformity, PMS plan
Clinical Evidence	Reliance on published literature, foreign approvals, or local clinical investigations if required	Mandatory clinical evaluation for all devices; clinical investigations for higher-risk; Post-Market Clinical Follow-up (PMCF) required
Quality Management System	ISO 13485 compliance mandatory	ISO 13485 widely expected; QMS audits by Notified Bodies
Approval Timelines	Class A/B: ~6–9 months; Class C/D: ~45 days initial scrutiny but often longer depending on complexity	Variable; timelines depend on Notified Body capacity and device class; generally longer due to stricter evidence requirements
Market Authorization	License valid in perpetuity with retention fees every 5 years	CE marking grants EU-wide market access; certificates subject to surveillance audits and renewals
Post-Market Surveillance	Materiovigilance Programme of India (MvPI), adverse event reporting, CAPA; evolving enforcement	Robust PMS system, vigilance reporting, Periodic Safety Update Reports (PSURs), UDI traceability, EUDAMED transparency
Market Scale (2024)	~USD 12 billion	~€142 billion

6. Conclusion

This comparative analysis of the regulatory approval processes for medical devices in India and the European Union demonstrates that both jurisdictions are grounded in risk-based regulatory philosophy, yet differ substantially in the depth, structure, and lifecycle integration of regulatory oversight. While India's Medical Devices Rules, 2017 have significantly modernized the national framework and aligned it with international classification principles, the system remains comparatively streamlined in certain pre-market pathways, particularly for low- and moderate-risk devices. The tiered governance model involving State Licensing Authorities and the Central Licensing Authority reflects an approach designed to balance administrative feasibility with public health protection in a rapidly expanding market.

In contrast, the European Union's Medical Device Regulation (EU) 2017/745 represents a highly structured and evidence-intensive lifecycle regulatory model. The MDR emphasizes comprehensive technical documentation, mandatory third-party conformity assessment, strengthened clinical evaluation requirements,

post-market clinical follow-up, and proactive vigilance systems supported by traceability mechanisms such as Unique Device Identification. This approach enhances transparency and patient safety but is associated with increased compliance costs and extended approval timelines.

India offers relatively faster access pathways for lower-risk technologies, supporting domestic manufacturing growth and accessibility, whereas the EU prioritizes robust, continuous evidence generation and harmonized enforcement across Member States. Ultimately, both systems illustrate evolving regulatory science frameworks aimed at safeguarding patients while facilitating technological innovation in healthcare.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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