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# The Comparative Study on Performance of Selected Medial Devices Manufactured in India and Foreign Countries with Regulatory Affairs

**Vanapalli Gayatri, Yellanki Shiva Kumar*, Jamjala Naveen, Peddoju Jyothi, B. Anitha**

*Geethanjali College of Pharmacy, Keesara Mandal, Cheeriyal, Hyderabad, Telangana*

Corresponding Author: **Dr Yellanki Shiva Kumar**
Email: dryskgcp@gmail.com

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**Abstract:** The global medical device industry plays a pivotal role in modern healthcare, offering innovative solutions for diagnosis, treatment, and monitoring of various health conditions. With rapidly evolving technologies and increasing demand for quality healthcare, stringent regulatory frameworks have become essential to ensure the safety, efficacy, and quality of medical devices. This thesis presents a comprehensive comparative analysis of medical device regulations in India, the United States (US), and the European Union (EU), with particular emphasis on the performance, regulatory compliance, and market penetration of devices manufactured in these regions.

The study employs a qualitative research methodology, focusing on critical aspects such as classification systems, approval pathways, clinical data requirements, quality management systems (QMS), post-market surveillance (PMS), and innovation facilitation mechanisms. Through in-depth evaluation of the Medical Device Rules (MDR) 2017 in India, USFDA's regulatory provisions under 21 CFR, and the EU Medical Device Regulation (EU MDR 2017/745), the thesis identifies regulatory gaps, strengths, and harmonization opportunities. Key findings highlight that while the US and EU possess mature and globally harmonized frameworks with established clinical evidence requirements and robust PMS infrastructure, India's regulatory landscape, though improving, faces challenges including limited notified bodies, fragmented oversight, and inconsistent enforcement mechanisms. Case studies, including coronary stents, underscore differences in clinical validation, approval timelines, and international competitiveness.

The research concludes with policy recommendations for enhancing India's regulatory efficiency, strengthening digital and post-market infrastructure, and aligning more closely with global standards to ensure better device performance, patient safety, and international market access.

**Keywords:** Medical Device Regulation, USFDA, CDSCO, Regulatory Affairs, Device Classification, Post- Market Surveillance, Notified Bodies, Indian Medical Device Industry,

Clinical Evaluation, Global Harmonization

## INTRODUCTION

### Medical Devices

Medical devices range from basic products like catheters to advanced technologies such as drug-eluting stents. In 2003, the WHO proposed a standardized definition to distinguish medical devices from

pharmaceuticals, leading to the establishment of various national regulatory systems. While regions like the U.S., Canada, and the EU adopted harmonized approaches, India developed its own under the Drugs and Cosmetics Act. The global medical device industry saw a growth rate of 6-7% in 2009, with the Indian market reaching USD 6.0 billion in 2023 and projected to grow at a CAGR of 8.5%, potentially reaching USD 9.0 billion by 2028, despite a reliance on imports for 70% of demand.

### Device Classification

The Central Licensing Authority (CLA) in India classifies both medical devices (MDs) and in vitro diagnostic medical devices (IVDMDs) into four categories based on intended use, associated risk, and criteria outlined in the Indian Medical Device Rules (IMDR) [4]:

- **Class A**: Low risk
- **Class B**: Low to moderate risk
- **Class C**: Moderately high risk
- **Class D**: High risk

Generally, countries group devices into three or four classes depending on the level of health risk, as outlined in **Table 1.1**.

**Table 1.1: International Medical Device Classifications**

| Country | Risk-Based Classification |
|---|---|
| United States | I, II, III |
| Europe an Union | I, IIa, IIb, III |
| China | I, II, III, IV |
| Korea | I, II, III, IV |
| Japan | I, II, III, IV |
| India | A, B, C, D |
| Australia | I, IIa, IIb, III |

India's classification system mirrors this tiered approach, with categories ranging from Class A (low risk) to Class D (high risk). However, regulatory alignment remains a challenge, as in India several medical devices are regulated under the Drug Act, and in certain cases, devices are designated as "drugs" [5].

## METHODOLOGY

The primary objective of this study is to carry out a comprehensive qualitative assessment of medical device regulations in India, the United States (US), and the European Union (EU). The study will also conduct a comparative gap analysis to identify strengths, limitations, and alignment opportunities within Indian regulatory practices compared to international standards.

### U.S. Medical Device Regulatory Overview

The regulation of medical devices in the United States falls under the purview of the Food and Drug Administration (FDA), governed by the Federal Food, Drug, and Cosmetic Act (FD&C Act), originally enacted in 1938. The scope of medical device regulation was significantly expanded with the introduction of the Medical Device Amendments in 1976, which formally established FDA's authority to regulate devices before market entry.

### Approval Pathways under USFDA

Most devices in the US are cleared or approved through one of the following regulatory pathways: 510(k)Premarket Notification, Premarket Approval (PMA), Humanitarian Device Exemption (HDE), De Novo Classification, Investigational Device Exemption (IDE)

### EU Medical Device Regulation

The regulation of medical devices in the European Union (EU) has evolved considerably over the past three decades, transitioning from early directives to a unified regulatory framework aimed at enhancing device safety, transparency, and market surveillance.

### Historical Evolution of EU Regulations

The regulation of medical devices in Europe began with the adoption of the Medical Device Directive (MDD) 93/42/EEC in 1993, which harmonized safety and performance requirements across EU member states. The directive was amended several times to broaden its scope and refine classification and approval procedures:

### Medical Device Regulation (EU MDR) 2017/745

The EU MDR represents a fundamental shift from the directive-based system of the MDD to a more robust and centralized regulatory framework. It applies to all medical devices intended for the European market and emphasizes clinical evaluation, safety monitoring, and lifecycle oversight.

### Indian Medical Device Regulation

India is one of the fastest-growing markets for medical devices, with over 800 types of devices manufactured domestically. Despite this, the Indian medical device market has long been dominated by imports, with a significant portion of high-risk and precision devices sourced from foreign manufacturers. Historically, the regulatory landscape for medical devices in India was limited and fragmented, governed by the Drugs and Cosmetics Act, 1940, which only covered 15 categories of devices categorized as "drugs." The remainder of the medical devices remained largely unregulated for decades.

### Medical Devices Rules, 2017

To address these gaps and align Indian regulations with global practices, the Government of India introduced a comprehensive framework titled the Medical Devices Rules (MDR), 2017, notified under the Drugs & Cosmetics Act on 31st January 2017 and enforced from 1st January 2018. This regulation marked a transformative shift in the Indian regulatory approach and was designed in synchronization with the Global Harmonization Task Force (GHTF) principles.

The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, serves as the national regulatory authority. Within CDSCO, the Medical Device and Diagnostics Division is responsible for policy formulation, implementation, and monitoring. The Drug Controller General of India (DCGI) functions as the apex licensing authority.

## RESULTS AND DISCUSSION

**Comparative Review of Medical Device Regulations in India, US, and EU**

| Comparative Factor | India | U.S. | Europe |
|---|---|---|---|
| Regulatory Authority | CDSCO/DCGI | FDA (CDRH) | EMA & MemberState Authorities |
| Regulation Name | Medical Device Rules, 2017 | 21 CFR (820 etc.) | MDR 2017/745, IVDR 2017/746 |
| Device Classes | Class A–D | Class I–III | Class I, IIa, IIb, III |
| Approval Pathways | Licensing & Clinical Evaluation | 510(k), PMA, HDE | CE Mark via NB |
| QMS | ISO 13485 / BIS | 21 CFR 820 | ISO 13485 / MDR Annexes |
| Tech Assessment Body | CDSCO/Notified Bodies | FDA | Notified Bodies / Competent Authority |
| Clinical Data | Class C & D only | Class II & III | Class IIb & III |
| In-Country Trials | Not always mandatory | Mandatory (IRB) | Required for Class IIb & III |
| Fees | $1000–$5000 (Import) | $4690–$234,495 | Member-state dependent |

| | | | |
|---|---|---|---|
| License Validity | 5 years | Indefinite | 3 years or indefinite (Class-dependent) |
| Submission Format | Paper/Electronic | Electronic | Electronic |
| Final Outcome | Import/Manufacturing License | Clearance/Approval Letter | CE Mark |

Regulatory frameworks serve as a backbone for safeguarding public health while promoting innovation. Although India has streamlined its process, further harmonization, transparency, and post-market surveillance reforms are essential. As global healthcare challenges evolve, fostering alignment across jurisdictions and strengthening internal review mechanisms will ensure better market access and patient safety. The convergence of regulations, coupled with real-world evidence and digital innovation, is the future of efficient, safe, and global-ready medical device development.

**Comparative Regulatory Framework Analysis**

| **Parameter** | | **India (CDSCO/MDR 2017)** | **United States (USFDA)** | **European Union (EU MDR)** | |
|---|---|---|---|---|---|
| Regulatory Authority | | CDSCO / DCGI | USFDA | European Commission/ Notified Bodies | |
| Classification System | | Class A to D (risk-based) | Class I to III | Class I, IIa, IIb, III | |
| Primary Legislation | | MDR 2017 | 21 CFR Part 800861 | Regulation 2017/745 | (EU) |
| Approval Pathways | | CLAA/DCGI licensing | 510(k), PMA, HDE, De-Novo, IDE | CE Certification via Notified Bodies | |
| Clinical Requirement | Data | For Class C & D | Required for PMA,not for 510(k) | Required for Class IIa and above | |
| Post-Market Surveillance (PMS) | | Yes, for Class C & D | Mandatory for Class II/III | Required for all device classes | |
| Device Innovation Support | | Limited | Breakthrough Devices Program | Notified consultation model | body |
| Predicate Device Mechanism | | Emerging | Strong (510(k)) | CE equivalency (limited under MDR) | |

**5.5. Comparative Regulatory Framework Analysis**

| **Parameter** | **India CDSCO(2017)** | **UnitedStates (USFDA)** | **European Union (EU MDR)** |
|---|---|---|---|
| Regulatory Authority | CDSCO / DCGI | USFDA | European Commission/ Notified Bodies |
| Classification System | Class A to D (riskbased) | Class I to III | Class I, IIa, IIb, III |
| Primary Legislation | MDR 2017 | 21 CFR Part 800–861 | Regulation (EU) 2017/745 |
| Approval Pathways | CLAA/DCGI licensing | 510(k), PMA, HDE, De Novo, IDE | CE Certification via Notified Bodies |
| ClinicalData Requirement | For Class C & D | Required for PMA, not for 510(k) | Required for Class IIa and above |
| Post-Market Surveillance (PMS) | Yes, for Class C & D | Mandatory for Class II/III | Required for all device classes |
| Device | Limited | Breakthrough Devices | Notified body consultation |

| Innovation Support | | Program | model |
|---|---|---|---|
| Predicate Device Mechanism | Emerging | Strong (510(k)) | CE equivalency (limited under MDR) |

**Key Observations from Comparative Analysis**

India

- The introduction of MDR 2017 significantly improved the Indian regulatory landscape.
- However, regulatory capacity, limited notified bodies, and longer approval timelines for new devices (especially Class C and D) hamper innovation.
- India's cost-control focus results in classifying some high-end devices as
- "drugs" under

NPPA, which adds dual regulatory hurdles.

United States

- Offers multiple pathways tailored to device risk and novelty.
- 510(k) clearance remains the fastest route to market but may compromise thorough clinical evaluation.
- PMA pathway, although stringent, ensures rigorous safety and efficacy validation through clinical trials.

European Union

- EU MDR enforces strong post-market safety requirements, high transparency, and lifecycle oversight.
- The system is robust but complex, especially after MDR 2017/745 enforcement, increasing cost and regulatory burden on small manufacturers.

**Case Study Comparison: Coronary Stents**

| **Brand /Origin** | **Meril Myval (India)** | **Medtronic Resolute (USA)** | | **Biotronik Orsiro (EU)** | |
|---|---|---|---|---|---|
| Approval Process | CDSCO + Local Clinical Trial | 510(k) with limited human data | | CE Mark Notified Body | via |
| Clinical Evaluation | India-specific trials (TAVR) | International center | multi- | EU registrybased evaluation | |
| Time to Market (Avg.) | 18–24 months | 6–12 months (510k) | | 12–24 months | |
| Post-Market Study | Limited | Required for PMA | | Mandatory PMS &PSUR | |
| Market Cost (INR/USD) | ₹70,000 ($850) | ₹1,20,000 ($1,500) | | ₹1,10,000 ($1,400) | |

Note: While Indian stents are cost-effective, they often lack comprehensive international clinical validation, impacting global competitiveness.

**Regulatory Gaps Identified in India**

| Regulatory Weakness | Impact |
|---|---|
| Limited number of certified Notified Bodies | Slows down device audits and certifications |
| Lack of centralized electronic submission platform | Delays application review and transparency |
| Insufficient clinical trial infrastructure | Affects real-world safety data generation |
| Dual regulatory overlap for drugclassified devices | Creates ambiguity in compliance and pricing control |
| Inadequate PMS enforcement | Weakens post-marketing risk detection |

## CONCLUSION

The comparative study of medical device regulatory frameworks across India, the United States, and the European Union reveals significant variations in regulatory maturity, implementation rigor, and global alignment. While the United States and the European Union have developed highly structured, well-established systems over decades—anchored in risk- based classification, robust premarket evaluation, and post-market surveillance mechanisms India's regulatory ecosystem remains in a state of rapid evolution.

The introduction of the Medical Device Rules (MDR), 2017 in India marked a pivotal step toward global harmonization and regulatory clarity. These rules aligned domestic regulations with international best practices such as ISO 13485 and WHO GRP principles. The adoption of a risk-based classification (Classes A–D), establishment of centralized authorities like CDSCO/DCGI, and provisions for clinical trials and quality management systems demonstrate India's growing regulatory competence. However, the country still faces notable challenges, including a limited number of Notified Bodies, inadequate post-market surveillance (PMS) infrastructure, and regulatory overlaps for devices classified under the Drugs and Cosmetics Act.

In contrast, the USFDA follows a flexible, innovation-friendly approach with multiple regulatory pathways (e.g., 510(k), PMA, De Novo) tailored to device risk and novelty. Its emphasis on clinical evidence, post-approval surveillance, and integration of digital health solutions sets a global benchmark. Similarly, the EU MDR (Regulation 2017/745) has enhanced device oversight through comprehensive lifecycle management, mandatory CE marking via Notified Bodies, and standardized conformity assessments. Despite these strengths, the EU's regulatory burden postMDR implementation has significantly increased, especially for small and medium enterprises.

The analysis of specific case studies, such as coronary stents, illustrates how Indian devices are competitively priced yet lack international clinical validation, limiting global market penetration. Conversely, US and EU-manufactured devices benefit from broader regulatory acceptance and global competitiveness due to stronger clinical backing and regulatory reciprocity.

**Key areas of regulatory divergence include:**

- Device classification frameworks (e.g., four-tier in India vs. three-tier in the US).
- Regulatory pathways (e.g., 510(k) vs. CE Mark vs. CDSCO licensing).
- Clinical data requirements, especially for moderate-risk devices.
- Post-market surveillance intensity and real-time reporting mechanisms.

**To bridge these gaps, India must focus on:**

- Strengthening notified body capacity and digital regulatory infrastructure.
- Establishing centralized PMS systems and real-time adverse event monitoring.
- Streamlining licensing processes to eliminate redundancy and regulatory overlaps.
- Promoting indigenous innovation and clinical research to enhance global acceptability.

In conclusion, while India's MDR 2017 offers a solid foundation, continuous refinement, global benchmarking, and cross-jurisdictional harmonization are essential to elevate its regulatory landscape. Aligning with global standards not only ensures patient safety and product efficacy but also positions India as a competitive hub for high-quality, affordable medical devices in the global healthcare ecosystem.

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