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Review Paper

A Comparative Overview of Medical Device Regulatory Framework in the United States, European Union, and Russia

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ABSTRACT

Medical devices play a vital role in modern healthcare by supporting diagnosis, treatment, monitoring, and prevention of diseases. Due to potential risks associated with their use, robust regulatory frameworks are required to ensure safety, quality, and performance. This review paper presents a comparative analysis of medical device regulatory systems in the United States (US), European Union (EU), and Russia. The US follows a centralized system regulated by the Food and Drug Administration (FDA) using risk-based classification and approval pathways such as 510(k) and Premarket Approval (PMA). The EU regulates devices under the Medical Device Regulation (EU) 2017/745 (MDR), emphasizing conformity assessment through Notified Bodies and mandatory CE marking. Russia regulates medical devices through Roszdravnadzor, requiring state registration, local testing, and conformity assessment under the Eurasian Economic Union (EAEU) framework. This comparative study highlights similarities and differences in classification, approval procedures, clinical evidence requirements, and post-market surveillance systems. Understanding these regulatory variations is essential for manufacturers seeking global market access

INTRODUCTION

By aiding in the prevention, diagnosis, monitoring, treatment, and rehabilitation of illnesses and medical conditions, medical devices are essential to contemporary healthcare. A medical device is defined by the U.S. Food and Drug Administration (FDA) as an instrument, apparatus, implement, machine, implant, in vitro reagent, or software that is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease without primarily accomplishing its intended purpose through chemical action or metabolism. Regulatory bodies have set up risk-based regulatory systems to guarantee the safety, quality, and performance of medical devices both before and after marketing because they differ greatly in

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terms of their intended purpose, complexity, and associated risk. Even though many nations adhere to globally accepted standards, firms looking to access international markets face substantial obstacles due to variations in laws, categorisation standards, conformity assessment processes, and post-market surveillance regulations. With a focus on regulatory bodies, device classification systems, approval processes, quality management standards, and post-market surveillance mechanisms, this review offers a comparative overview of the medical device regulatory frameworks in the US, EU, and Russia. (1) (2) (3)

2. MEDICAL DEVICE REGULATORY FRAMEWORK IN THE UNITED STATES

2.1 Regulatory Authority

Medical devices in the US are regulated by the **Food and Drug Administration (FDA)** under the **Federal Food, Drug, and Cosmetic Act (FD&C Act)**. The **Center for Devices and Radiological Health (CDRH)** is responsible for pre-market and post-market oversight.

2.2 Classification System

US medical devices are classified into three categories based on risk:

Table 1: Medical Device classification System in US (1)

Risk Class	Risk Level	Examples	Regulatory Pathway / Registration Complexity
Class I	Lowest risk	Elastic bandages, examination gloves, manual surgical instruments, tongue depressors	General Controls; most devices are exempt from 510(k), simplified registration
Class II	Moderate risk	Infusion pumps, powered wheelchairs, blood pressure monitors, surgical drapes	General and Special Controls; usually requires **510(k) Premarket Notification** demonstrating substantial equivalence
Class III	Highest risk	Implantable pacemakers, heart valves, coronary stents, implantable defibrillators	**Premarket Approval (PMA)** with extensive clinical evidence, scientific review, and FDA approval

2.3 Approval Pathways

- **510(k) Premarket Notification:** Needs substantial equivalency to a predicate device for the majority of Class II devices.
- **Premarket Approval (PMA):** Needs substantial clinical evidence for Class III devices.

2.4 Post-Market Surveillance

- Monitoring After the Market Reporting Medical Devices (MDR).
- Adverse event reporting, inspections, and recalls.

2.5 Recent Developments

36 original Premarket approval (PMA) applications and 2,180 Premarket approval supplements were authorised by the USFDA's CDRH (Centre for Medical Devices and Radiological Health) in 2023. This significantly contributed to the 5,807 marketing submissions that were approved in 2023. (4)

2.6 Amendments

2023 Pulse Oximeter Draft Update New recommendations for improving the accuracy of pulse oximeters, especially with regard to different skin tones. It is anticipated that 21 CFR Part 820 will be modified to conform to ISO 13485:2016, a global medical device quality management system standard, in order to boost efficiency, lower regulatory barriers, and harmonise international standards.

Amendment: New recommendations to improve device performance across a range of demographics and lessen health inequalities. (5)

3. MEDICAL DEVICE REGULATORY FRAMEWORK IN THE EUROPEAN UNION

3.1 Regulatory Authority

In the EU, medical devices are subject to **Regulation (EU) 2017/745 (MDR),** which is enforced by **National Competent Authorities** and evaluated by Notified Bodies. (2)

3.2 Classification System

EU devices are classified into four risk-based classes:

Table 2: Medical Device classification System in EU (2)

Risk Class	Risk Level	Examples	Conformity Assessment / Registration Complexity
Class I	Lowest risk	Non-invasive instruments, wheelchairs, reusable surgical instruments, hospital beds	Self-declaration by manufacturer (except sterile, measuring, or reusable surgical instruments); CE marking
Class IIa	Low–Moderate risk	Ultrasound equipment, dental fillings, hearing aids, hypodermic needles	Notified Body assessment required; Technical Documentation review; CE marking
Class IIb	Moderate–High risk	Ventilators, infusion pumps, long-term contact lenses, intensive care equipment	Comprehensive Notified Body conformity assessment, Quality Management System audit, CE marking
Class III	Highest risk	Implantable pacemakers, coronary stents, heart valves, implantable neurostimulators	Most stringent conformity assessment, Clinical Evaluation, Notified Body review, Expert Panel consultation (where applicable), CE marking

3.3 CE Marking

CE certification permits free market access inside the EU and attests to adherence to safety and performance standards.

3.4 Clinical Evaluation & PMS

- The Clinical Evaluation Report (CER) is required.
- **Post-Market Clinical Follow-up** (PMCF) and **Post-Market Surveillance** (PMS)
- EUDAMED-based vigilance reporting.

3.5 Recent Developments

The European Union's Medical Device Regulation (MDR), which went into force in April 2017, altered the European legal framework for medical devices and imposed a number of new obligations on the European Medicines Agency (EMA) and the state competent authorities. (4)

3.6 Amendments

a) EU Regulation 2024/1860-2024: Amendment: Extended transition periods for some IVDs and phased implementation of EUDAMED (European Database on Medical Devices).

Objective: Promote transparency and expedite post-market surveillance and device tracing. (6)

b) Medical equipment, especially Class I sterile/measuring devices, have longer transition periods under Regulation 2023/607-2023 of the EU Amendment: MDR (EU) 2017/745.

Objective: Due to resource constraints and certification concerns, give manufacturers extra time to adapt to MDR. (7)

4. MEDICAL DEVICE REGULATORY FRAMEWORK IN RUSSIA (8)

4.1 Regulatory Authority

- The Russian Ministry of Health's Federal Service for Surveillance in Healthcare (Roszdravnadzor) is in charge of regulating medical devices.
- Device registration, market authorisation, inspections, post-market surveillance, and vigilance operations fall under the purview of Roszdravnadzor.
- In Russia, only gadgets that have a current Registration Certificate may be sold.

4.2 Legal Framework

- Federal Law No. 323-FZ " On the Fundamentals of Health Protection of Citizens."
- Government Decree No. 1416 about medical device registration.
- Ministry of Health Order No. 4n (nomenclature and classification of medical devices).
- Applicable GOST and GOST ISO standards.
- Regulations for uniform registration under the Eurasian Economic Union (EAEU).

4.3 Classification System

Russian medical devices are classified into four risk classes:

Table 3: Medical Device classification System in RUSSIA (9. https://traccglobal.com/russia-medical-device-registration/)

Risk Class	Risk Level	Examples	Registration Complexity
Class I (Non-Sterile)	Lowest risk	Bandages, manual instruments, tongue depressors	Simplified / fast-track available
Class IIa	Low-moderate risk	Ultrasound gel, ECG electrodes, blood pressure cuffs	Standard multi-stage
Class IIb (Sterile)	Moderate-high risk	Infusion pumps, ventilators	Full review + site inspection (from 2024)
Class III	Highest risk	Implantable pacemakers, coronary stents, spinal implants	Full review + clinical + site inspection

4.4 Quality Management System (QMS)

- Manufacturers must put in place a Quality Management System that complies with globally accepted standards like **ISO 13485.**
- During the registration process, adherence to relevant Russian and EAEU **quality standards** is assessed.

4.5 Post-Market Surveillance

Manufacturers are responsible for:

- Monitoring After the Market Manufacturers are in charge of: Keeping an eye on the functioning and safety of devices.
- Reporting unfavourable incidents.
- Taking corrective and preventative measures (CAPA).
- When required, field safety corrective actions (FSCA) and product recalls.

- Adhering to regulations for the duration of the product's lifecycle.

5. COMPARATIVE ANALYSIS OF MEDICAL DEVICE REGULATIONS

Table 4: Comparison of Medical Device Regulations in US, EU and Russia (2) (3) (4)

Regulatory Aspect	United States (US)	European Union (EU)	Russia
Regulatory Authority	Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA)	National Competent Authorities (NCAs) and Notified Bodies onder de EU MDR	Federal Service for Health Surveillance (Roszdravnadzor)
Primary Legislation	Federal Food, Drug, and Cosmetic (FD&C) Act	Medical Device Regulation (EU) 2017/745 (MDR)	Government Decree No. 1416, Federal Law No. 323-FZ, and EAEU Regulations
Regulatory Approach	Federal regulatory system that is centralized	Decentralized system with Notified Bodies evaluating compliance	Roszdravnadzor's centralized state registration system
Device Classification	Class I: Low Risk; Class II: Moderate Risk; and Class III: High Risk	Class I, Class IIa, Class IIb, and Class III	Class I, Class IIa, Class IIb, and Class III
Risk-Based Classification	Yes	Yes	Yes
Approval/Registration Pathway	Premarket Approval (PMA), De Novo, and 510(k)	CE Marking following a conformity evaluation	Roszdravnadzor issued the State Registration Certificate.
Conformity Assessment	FDA review	Carried out by Notified Bodies	Carried out by Roszdravnadzor and approved specialized organizations
Clinical Evidence Requirement	While many 510(k) devices have minimal requirements, PMA needs substantial clinical evidence.	PMCF is necessary for relevant devices, and Clinical Evaluation Reports (CERs) are mandatory.	Depending on the device class, local clinical studies and clinical evaluation are necessary.
Quality Management System (QMS)	21 CFR Part 820 (QSR); alignment with ISO 13485	Manufacturers are expected to adhere to ISO 13485.	ISO 13485 and relevant Russian/EAEU quality standards
Technical Documentation	Risk analysis, design dossier, device description, labeling, and performance information	Risk Management File, CER, and Technical Documentation (Appendices II and III of MDR)	Technical documents, testing reports, risk management, labeling, and IFU are all included in the registration dossier.
Local Authorized Representative	Foreign producers must comply; local manufacturers are exempt.	Non-EU manufacturers must have a European Authorized Representative.	Required for overseas producers
Unique Device Identification (UDI)	FDA UDI System Requirement	Required by EU MDR	Gradual adoption in accordance with EAEU rules
Post-Market Surveillance (PMS)	Recalls, inspections, adverse event reporting,	PMS, PMCF, EUDAMED, and vigilance reporting	Field Safety Corrective Actions (FSCA), CAPA, adverse event reporting,

	and medical device reporting (MDR)		state monitoring, and recalls
Market Authorization	FDA Approval or Clearance	CE Certification	Certificate of Registration
Regional Market Access	Only in the United States	Every member state of the EU/EEA having a CE mark	Russia and other EAEU members via the EAEU framework
Major Strengths	Comprehensive post-market surveillance, comprehensive scientific evaluation, and transparent review processes	Unified market access throughout Europe; globally acknowledged CE Marking	Thorough state supervision and harmonization via EAEU
Key Challenges	Protracted PMA procedure for devices at high risk	MDR's increased paperwork requirements and the Notified Body's capability limitations	complicated registration procedure, requirements for local testing, and paperwork in Russian

6. CASE STUDY: IMPORTANCE OF POST-MARKET SURVEILLANCE IN MEDICAL DEVICE REGULATION (10)

A notable example highlighting the importance of effective post-market surveillance is the **MitraClip® Delivery System**, a medical device used to treat mitral regurgitation. Although the device successfully met pre-market quality and regulatory requirements, post-market reports identified instances of clip detachment, leading to serious complications, including patient deaths. As a result, specific batches manufactured between **July and August 2015** were recalled, demonstrating the critical role of adverse event reporting, continuous safety monitoring, and timely regulatory action in protecting patient safety.

Similarly, analysis of the **US FDA Manufacturer and User Facility Device Experience (MAUDE)** database identified **31 fatal and 1,353 non-fatal adverse events** associated with laparoscopic trocars between **1997 and 2002**. These findings emphasize the need for comprehensive adverse event reporting systems and robust post-market surveillance to detect device-related risks, improve regulatory oversight, and enhance patient safety.

CONCLUSION

Although the US, EU, and Russia aim to ensure medical device safety and performance, their regulatory approaches differ significantly. The US system is centralized and science-driven, the EU system is conformity-based with third-party assessments, and the Russian system emphasizes state control and local evaluation. Manufacturers must adapt regulatory strategies according to regional requirements to achieve successful global market access.

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