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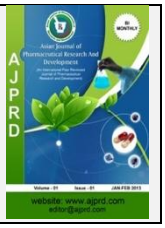

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Review Article

EU MDR Regulatory Update and Compliance Strategies

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A B S T R A C T

The formation of the European Union (EU) medical device regulatory framework was largely driven by significant public health crises, including the thalidomide tragedy of the 1950s and 1960s, which revealed the dangers of insufficient oversight in both pharmaceuticals and medical devices. In response, the EU introduced a series of directives, starting with the Medical Device Directive (MDD) in 1993, aimed at harmonizing regulations across member states and ensuring patient safety. Early challenges in these regulations, such as insufficient clinical data and weak post-market surveillance, led to ongoing revisions, particularly as medical technology evolved. The thalidomide disaster highlighted the need for stringent, independent oversight, pushing the EU toward more rigorous standards for clinical evidence, post-market monitoring, and oversight of Notified Bodies independent organizations that assess device conformity.Subsequent medical device failures, such as the PIP breast implant scandal and issues with metal-on-metal hip implants, further exposed gaps in regulation. These prompted the introduction of the Medical Device Regulation (MDR) in 2017, emphasizing enhanced clinical evidence, stricter post-market surveillance, and greater transparency. Key provisions include device classification based on risk, mandatory Unique Device Identification (UDI) for traceability, and a centralized database (EUDAMED) for improved visibility. This ongoing regulatory evolution ensures the safety and efficacy of medical devices across the EU, responding to technological advances and increasing public demand for stronger protections in healthcare.

Key words: Thalidomide tragedy,public health crises,medical device failures

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INTRODUCTION

The regulation of medical devices in the European Union (EU) has evolved significantly in response to historical health crises, technological advancements, and increasing demands for patient safety.Triggered by tragedies like the thalidomide disaster, the EU recognized the need for robust oversight, leading to the introduction of early directives such as theActive Implantable Medical Device Directive(AIMDD)Medical Devices Directive(MDD) and In Vitro Diagnostic Directive (IVDD) between 1990 and 1998. However, these frameworks revealed shortcomings in clinical evidence requirements, post-market surveillance, and consistency among Notified Bodies.Subsequent scandals, including the PIP breast implant and metal-on-metal hip failures, further exposed regulatory gaps, prompting the development of the more comprehensive Medical Device Regulation (MDR 2017/745).This regulation emphasizes stricter pre-market assessment, enhanced clinical evaluation, mandatory Unique Device Identification (UDI), and improved transparency through systems likeEuropean Database on Medical Devices (EUDAMED).It also integrates risk management practices aligned withinternational standard of organisation(ISO) standards and is supported by detailed guidance from the European Commission and theMedical Device Coordination Group(MDCG).Through continuous updates and harmonization across member states, the EU aims to ensure that medical devices are safe, effective, and reliably monitored throughout their lifecycle.

History of Medical Device Directives Formation and Tragedies

The European Union established its medical device regulatory framework primarily in response to major public health tragedies, most notably the thalidomide disaster in the

late 1950s and early 1960s, which demonstrated the dangers of inadequate oversight for pharmaceuticals and, by extension, for medical devices. This tragedy highlighted the need for stricter controls and an independent regulatory authority to protect patient safety and restore public trust.(1)

The initial regulatory structure for medical devices in the EU comprised three key directives:

- Active Implantable Medical Device Directive (AIMDD, 1990)
- Medical Devices Directive (MDD, 1993)
- In Vitro Diagnostic Directive (IVDD, 1998)

These directives aimed to harmonize requirements across EU Member States, facilitate the free movement of goods, and ensure a high level of patient and user protection. However, early implementations had shortcomings:

- Many devices entered the market without robust clinical data requirements, especially lower-risk devices.
- Lapses in the assessment of clinical data by Notified Bodies (independent organizations designated to assess device conformity) were observed.
- Incident reporting and post-market surveillance mechanisms were underdeveloped.

As technology advanced and new safety risks emerged (e.g., the rapid evolution of software as medical devices), it became clear that existing regulations were insufficient for modern and complex innovations. Tragedies involving device failures, as well as a lack of harmonized vigilance, prompted reviews and amendments that introduced:

- Stricter requirements for clinical evidence (from 2007 onward)
- A mandatory vigilance system for adverse incidents
- Greater oversight of Notified Bodies

The Thalidomide Scandal for Implementing Regulatory Guidelines

The thalidomide scandal of the late 1950s and early 1960s profoundly influenced the development of European medical device regulation by exposing the dangers of minimal oversight and the need for strong, science-based, pre-market control over health products.(2-4)

Key influences include:

Catalyst for Stronger Regulation: The tragedy highlighted the lack of mandatory safety and efficacy testing before market approval—thalidomide had been widely sold across European countries without adequate studies or regulatory rigor. This undermined public trust and made clear the necessity for robust, independent regulatory authorities.

Patient Safety as a Priority: In response, EU legislation shifted from relying largely on manufacturer assurances to requiring independent assessments, particularly for higher-risk medicines and, by parallel, for medical devices. The thalidomide disaster became the worst-case scenario the system was designed to prevent.

Evolution of Standards: The EU's earliest relevant law (Directive 65/65/EEC, 1965) aimed to ensure that only drugs (and, by analogy in evolving practice, devices) demonstrated to be safe and effective could be marketed. Subsequent medical device directives (e.g., AIMDD 1990, MDD 1993) and eventually the Medical Device Regulation (MDR 2017) were directly shaped by lessons from the scandal, focusing on harmonized safety, performance, and post-market vigilance mechanisms.

Regulatory Structure: The scandal established the expectation for a knowledgeable regulatory body to decide which products reach patients, eventually leading to the creation of pan-European regulators and a structured approach to device oversight.

Safety and Confirmity Standards In Eu Medical Device Laws

Past crises—such as the thalidomide tragedy, the Poly Implant Prothèse (PIP) breast implant scandal, and failures with metal-on-metal hip implants—have driven major reforms in European medical device legislation, leading to much stricter safety and conformity standards.(5,6)

Key effects of these crises on EU medical device laws include:

Stronger Pre-market Scrutiny: Major public health failures prompted the requirement that all medical devices undergo independent safety and performance assessments before market entry, especially for higher-risk devices.

More Demanding Clinical Evidence: Regulations now require more robust clinical data to demonstrate not only "safety and performance as intended," but also clear "clinical benefit"—raising the bar for product approval.

Enhanced Post-market Surveillance: Manufacturers must establish comprehensive post-market surveillance and risk management plans, including faster reporting timelines for adverse events (e.g., within 15 days for serious incidents).

Increased Transparency: Regulations mandate public summaries of safety and clinical performance for high-risk devices and greater access to conformity assessment data via public databases like EUDAMED.

Tighter Notified Body Oversight: There is now stricter oversight of the independent organizations (Notified Bodies) that issue CE markings, aiming to prevent lapses seen in prior scandals.

Rapid Standards and Adaptation in Emergencies: During acute crises, such as the COVID-19 pandemic, the EU expedited harmonized standards (ENs) for essential medical products, enabling speedier conformity assessment while maintaining safety.

Formation of Medical Device Directives

The history of medical device directives is centre on the development of regulations that ensure the safety and performance of medical devices across the European Union (EU). These regulations have evolved over time to address the increasing complexity of medical technology and to create a unified approach to device safety and efficacy.(7-10)

1. Pre-1980s: Lack of Uniform Regulations

Before the 1980s, there were no comprehensive regulations governing medical devices in Europe. The safety and performance of medical devices were subject to national regulations,which varied significantly between countries. This created barriers to the free movement of medical devices within the EU.

2. 1980s: Early Efforts for Standardization

The need for uniform standards led to the early discussions and efforts to create EU-wide regulations for medical devices. During this period, the European Economic Community (EEC), the precursor to the EU, began to acknowledge the importance of medical device safety and set the groundwork for harmonized regulations.

3. 1990: First Medical Device Directive (MDD) 90/385/EEC

In **1990**, the EU introduced the **Medical Device Directive (MDD) 90/385/EEC**, which was a significant milestone in medical device regulation. It aimed to create a single market for medical devices by setting common standards for the safety and performance of devices sold in EU member states. The directive required manufacturers to demonstrate that their devices met essential safety and performance requirements and to undergo conformity assessment procedures.

4. 1993: Active Implantable Medical Devices (AIMD) Directive

In **1993**, the **Active Implantable Medical Device Directive (AIMD) 90/385/EEC** was introduced, focusing on implantable medical devices powered by electricity or another energy source. This directive complemented the MDD and added specific requirements for these high-risk devices, ensuring their safety and performance.

5. 2000: In Vitro Diagnostic Devices (IVDD) Directive

In **2000**, the **In Vitro Diagnostic Devices Directive (IVDD) 98/79/EC** came into effect. This directive set out regulatory requirements for medical devices that were used to perform diagnostic tests on samples taken from the human body (e.g., blood tests, urine tests). Like the MDD, the IVDD aimed to ensure safety and reliability but focused specifically on diagnostic devices.

6. 2007-2017: The Revision of MDD

The MDD was revised several times to adapt to technological advancements and improve safety standards. In **2007**, the European Commission began an initiative to revise the MDD in response to challenges such as concerns about patient safety, increased complexity of medical devices, and a growing number of high-risk devices being introduced to the market.

DIRECTIVES framed till 2007

M1-COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

M2-COUNCIL DIRECTIVE 93/68/EEC of 22 July 1993 concerning IV medical devices

M3-COUNCIL DIRECTIVE OF REGULATION 1882/2003 of EU parliament and the council

M4- COUNCIL DIRECTIVE OF REGULATION 2007/47/EC of EU parliament and the council

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the proposal from the Commission. In cooperation with the European Parliament. Having regard to the opinion of the Economic and Social Committee

The content and scope of the laws, regulations, and administrative provisions in force in the Member States about the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community.

Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, about the use of medical devices should be harmonized to guarantee the free movement of such devices within the internal market.

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive.

The Members Agreement to the Establishment of Legislations For Harmonisation In The Eu Council

The European union has a formed stable partnership after World War 2 and harmonised by 28 member states to make medical directives during committee has chaired to implement a special regulation to the health safety.

The result was affected by joining countries which had different categories to make equal distribution directive in the EU which has formed by the EEC.

Austria,Belgium,Bulgaria,Croatia,Cyprus,Czechia,Denmark, Estonia,Finland,France,GermanyGreece,Hungary,Ireland,Italy,Latvia,Lithuania,Luxembourg,Malta,Netherlands,Poland, Portugal,Romania,Slovakia,Slovenia,Spain,Sweden

The essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety.

Classes for Medical Devices

Class 1 devices can be followed general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products.

Class 2a devices can be followed general rule, under the intervention of a notified body should be compulsory at the production stage.

Class 2b and class 3 devices can be followed which constitute a high-risk potential, inspection by a notified body is required about the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization regarding conformity is required for them to be placed on the market.

The CE mark must indicate to generate marketing approval as to supply and sale the products within the EU as well as in various countries with obtaining international standards licences.

Medical devices (MDD)

Active implantable (AIMDD)

In vitro diagnostic (IVDD)

Whereas the protection of health and the associated controls may be made more effective by means of medical device vigilance systems which are integrated at Community level.

The European union have 23 articles and 12 annexures regarding on the directives.

Guidance documents on reference for MDD

Formation of Medical Device Regulations (11-14)

Revealed Regulatory Gaps and Device Failures: Crises such as the Poly Implant Prothèse (PIP) breast implant scandal and problems with metal-on-metal hip implants exposed insufficient pre-market scrutiny, weak post-market surveillance, and inconsistent assessments by Notified Bodies. These shortcomings drove calls for more robust, harmonized regulatory controls.

Stronger Requirements for Clinical Evidence: Initial directives allowed some devices to enter the market with minimal clinical data, especially lower-risk devices. Subsequent crises highlighted the need for demanding clinical evidence of safety and performance for all device classes.

Technological Advances: Rapid innovation—such as the rise of software as a medical device and more complex combination devices—outpaced the regulatory framework, necessitating updates to address new safety and performance challenges.

Harmonization and Transparency: Disparate national implementations and varying levels of Notified Body oversight led to uneven safety standards. Calls for pan-EU harmonization and increased transparency fuelled requirements for public safety summaries and centralized databases like EUDAMED.

International Pressure and Patient Protection: The global response to safety failures and a push from stakeholders—including patients, regulators, and industry—required the EU to update its regulations. High-profile device failures undermined public trust, making comprehensive reform essential for patient safety.

Key Elements of Current EU Medical Device Regulation (MDR)

The MDR is now the cornerstone of medical device regulation in Europe, and it features several key components:

Classification of Devices: Devices are classified into different categories (Class I, IIa, IIb, III) based on their risk, with stricter requirements for higher-risk devices.

Clinical Evidence: Medical devices must have robust clinical evidence to demonstrate their safety and performance, especially for higher-risk products.

Post-Market Surveillance: There are enhanced post-market surveillance and vigilance requirements to ensure ongoing safety once products are in use.

Notified Bodies: Independent organizations that assess and certify compliance with the regulations.

UDI System: Devices must carry a Unique Device Identifier for better tracking and traceability.

There are 123 articles and 17 annexures after transferring to the regulations.

Guidance Documents For Eu Medical Devices Regulations(15,16)

1. European Commission Guidance Documents

The European Commission provides a wide range of guidance documents aimed at explaining various provisions of the MDR and IVDR. These documents cover different aspects of medical device regulation, from the definition of medical devices to post-market surveillance requirements.

Guidance on Classification of Medical Devices: This document provides clarification on the classification rules of medical devices according to their risk profile (e.g., Class I, IIa, IIb, III).

Guidance on Clinical Evaluation and Clinical Investigation: Guidance regarding the clinical evaluation process and clinical investigations to ensure that the safety and performance of medical devices are proven.

Guidance on the Role of Notified Bodies: This document outlines the responsibilities and expectations for Notified Bodies when assessing medical devices for conformity.

Post-market Surveillance and Vigilance: These documents guide manufacturers on how to monitor the performance of devices after they have been placed on the market and the required reporting mechanisms in case of incidents or adverse events.

2. MDCG (Medical Device Coordination Group) Documents

The **MDCG** is an expert group established by the European Commission to provide technical support and advice on the implementation of the MDR and IVDR. The MDCG releases **guidance documents**, **position papers**, and **opinions** on specific issues related to medical devices and in vitro diagnostic devices.

"Guidance on the application of the MDR and IVDR". This guidance clarifies various provisions of the MDR and IVDR, providing practical advice for stakeholders.

"Post-market surveillance of medical devices". This guidance outlines best practices for post-market activities, including how to gather data on device performance once in use.

"Guidance on clinical investigations". Provides clarification on clinical investigation requirements, including those for Class III and implantable devices.

"General principles of clinical evaluation and clinical investigation of medical devices". Aimed at ensuring that the clinical evaluation process is understood and properly applied.

3. **European Database on Medical Devices (EUDAMED):** EUDAMED is a comprehensive database that is central to the EU's medical device regulation system, providing information on devices, manufacturers, Notified Bodies, and certificates. Guidance documents related to the use of this database are important for maintaining compliance.

QUALITY RISK MANAGEMENT FOR MEDICAL DEVICES

To provide quality risk management for compliance with the EU Medical Device Regulation (MDR 2017/745), manufacturers must adopt a systematic, continuous risk management process primarily based on the harmonized standard ISO 14971:2019.

Risk Management Plan: Establish and document a plan that defines the risk management strategy and activities throughout the device lifecycle, including risk identification, assessment, control, and review, forming part of a risk management file.

Risk Assessment: Identify known and foreseeable hazards related to the device during its intended use and reasonably foreseeable misuse. Then estimate and evaluate the associated risks by considering the probability and severity of harm.

Risk Control: Implement measures to eliminate or reduce risks as far as possible without negatively impacting the benefit-risk ratio. Controls must be verified for effectiveness, and any new hazards introduced by the controls themselves must be re-evaluated.

Residual Risk Evaluation: Since eliminating all risk is often impossible, assess the residual risks remaining after control measures. These residual risks must be evaluated to confirm they are acceptable or reduced as far as possible.

Benefit-Risk Analysis: For any residual risks that remain unacceptable, a documented benefit-risk analysis must demonstrate that the medical benefits outweigh these risks. Economic factors must not influence this analysis.

Continuous Monitoring and Updating: Risk management is iterative. Data and experience from production and post-market phases should be continuously evaluated to update risk assessments and controls accordingly.

Integration with Quality Management System (QMS): Risk management must be integrated within the QMS (such as ISO 13485), ensuring systematic oversight and compliance with regulatory requirements.

Updates On Medical Device Regulations For European Union(16,17)

1. **Extended Requirements for Electronic Instructions for Use (eIFU):** Regulation (EU) 2025/1234, published in June 2025, significantly amends rules on electronic instructions for use. Healthcare professionals now prefer electronic IFUs, and the regulation extends eIFU use to all medical devices and accessories intended for professional users, including legacy devices and those without a medical purpose such as cosmetic products with intended medical effects listed in Annex XVI.Manufacturers must provide electronic versions on their websites and a risk assessment for eIFU use is mandatory.
2. UDI (Unique Device Identification) marking becomes mandatory for MDR Class I medical devices and IVDR Class B and C in vitro diagnostic devices. Devices need valid UDI carriers on labels and packaging, and this also includes reusable devices in certain MDR classes that require direct marking.
3. Devices not compliant with UDI-DI requirements by this date may be considered non-compliant and face enforcement actions including supply disruptions and risk of losing CE marking.

Eu Medical Devices GMP Practices

- The EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) govern medical device manufacturing, incorporating GMP-like principles tailored for devices.
- Unlike pharmaceutical GMP (EudraLex Volume 4), medical devices follow a Quality Management System (QMS) approach aligned with ISO 13485 to ensure consistent manufacturing, quality control, traceability, and documentation.
- Key requirements include validated manufacturing processes, qualified personnel, supplier control, and thorough record-keeping.
- Post-market surveillance, vigilance, and continuous improvement are integral parts of compliance.
- Enforcement is through audits and conformity assessments by Notified Bodies and national authorities.

Protocols Implementation For Eu Medical Device Regulations (18-20)

The implementation of protocols for the European Union Medical Device Regulation (EU MDR) involves a structured, multi-step approach to ensure compliance with enhanced safety, clinical evidence, and post-market surveillance requirements. Key aspects of the implementation process include:

1. **Understanding the Regulation**: Manufacturers must fully comprehend the EU MDR's scope, changes from previous directives, and its impact on their products and business operations. This includes awareness of new definitions, classification changes, and overlaps with other regulations.
2. **Product Portfolio Review**: A thorough assessment of the entire medical device portfolio is necessary to determine if devices need reclassification or if accessories now fall under medical device definitions. This step ensures all products align with the new regulatory framework.

3. **Development of an EU MDR Strategy and Roadmap**: Organizations should establish a cross-functional implementation plan that integrates regulatory, commercial, R&D, and quality assurance teams to manage program governance and meet deadlines within transition periods.
4. **Quality Management System (QMS) Compliance**: The QMS must be updated to address MDR requirements, incorporating risk management, clinical evaluation processes, post-market surveillance (PMS) plans, and procedures for reporting serious incidents promptly.
5. **Clinical Evaluation and Evidence**: Enhanced clinical evidence demonstrating device safety and performance is required, including clinical investigations, post-market clinical follow-ups, and comprehensive clinical evaluation reports.
6. **Post-Market Surveillance and Reporting**: Manufacturers must implement robust PMS systems to monitor device performance continuously, analyse real-world data, and submit periodic safety update reports (PSURs) for certain device classes.
7. **Conformity Assessment and Notified Body Engagement**: To place devices on the EU market, manufacturers engage with designated notified bodies for conformity assessment against MDR requirements, including technical documentation review and certification.
8. **Organizational Alignment and Training**: Companies need strong project management, stakeholder communication, and staff training to embed MDR compliance effectively within operational processes.
9. **Regulatory Monitoring and Adjustment**: Ongoing monitoring of regulatory changes and implementation progress with capacity for GAP analysis and process redesign ensures sustained compliance.

Comparison of MDR and MDD of European union

The European Union (EU) Medical Device Regulations (MDR) and the Medical Device Directive (MDD) are both regulatory frameworks that govern medical devices within the European Union. The MDD was replaced by the MDR to improve patient safety and modernize the regulatory approach considering new technological advances and lessons learned from past issues. Below is a comparison of the two, focusing on key aspects that are relevant for a broader understanding of the regulatory evolution.

Table 1: Comparison of European union directives and regulations

MDD (93/42/EEC) as amended	**MDR (EU)2017/745) as amended**
First medical device directive in 1990 in section of 90/385/EEC.	In the year 2017 MDD has replaced with MDR which has fulfilled with stringent guidelines.
In ten years the major 2 directives were established as AIMD and IVDD	All countries were harmonized to establish this MDR in the European union regions
In the year 2007 implementing code of M for medical standard directives of regulations approved by European parliament.	latest guidelines were represented for all aspects.
The MDD has 23 articles	The MDR has 123 articles
Only 12 annexures were established lawfully	17 annexures were presented in 2017
Guidance documents were taken in the consideration as limited for the directives	Revised guidelines were modified and included latest regulations
The introduction of the Medical Device Directive (MDD) in 1993 marked the beginning of harmonized regulation across EU member states	Guidance documents were latest amended as considering coordination groups
The MDD has minimal stringent guidelines for making regulations The countries have different regulations for making coordination protocols	The regulatory landscape has since undergone important revisions, particularly with the adoption of the Medical Device Regulation (MDR) in 2017, which replaced the MDD, and the In Vitro Diagnostic Regulation (IVDR) for diagnostic devices
The MDD sets out 13 essential requirements (ERs) covering:	The MDR sets out 23 GSPRs covering:
General requirements, principal regarding risk	General requirements, principally regarding risk
Chemical, physical and biological properties	Products without a medical purpose;
Infection and microbial contamination	Chemical, physical and biological properties
Construction and environmental properties	Infection and microbial contamination
Devices with a measuring function	A statement that the device covered by the declaration is in conformity

CONCLUSION

The development of medical device rules in the European Union constitutes a concerted and forward-looking effort to respond to past public health issues and keep up with evolving medical technologies. The transition from scattered national control to a harmonized and holistic regulatory framework evidences the EU's commitment to protecting patient safety and public health. Through the focus on strong clinical assessment, sustained post-market monitoring, clear data systems, and risk-based management according to international standards, the new system efficiently addresses past weaknesses while laying the ground for future challenges. Combined, these actions encourage innovation, improve accountability, and reinforce public confidence in the safety and performance of medical devices throughout the European market.

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