Bridging the gap between Regulatory Compliance and Medical Device Safety: A Critical Study of the EU MDR Framework's effectiveness

Author Name: Danute Krakauskaite | Programme: MSc in Medical Device Technology and Business | Innopharma Education / Griffith College Dublin

Academic Year 2025–2026 | Supervisor: Martin Conneely | Contact: dkrakauskaite@yahoo.com

Introduction / Background

EU MDR: Compliance vs Real-World Safety

BACKGROUND: In 2017, the European Union introduced the new Medical Device Regulation (EU MDR) after several major medical device scandals. The more stringent MDR aimed to address major safety concerns and strengthen oversight. However, concerns remain regarding whether compliance with regulatory requirements actually reflects real-world device safety.

KEY EVIDENCE
- **Fewer than half** of stakeholders believed the MDR protects patients' and users' health (European Commission, 2025).
- MDR effectiveness: **71%+** notified bodies/public authorities vs **34%+** economic operators (European Commission, 2025).
- **28%** of participants (patients and informal carers, and patient organisations) reported medical-device safety issues since 2017 (European Patients' Forum, 2024).
- Recalls: **3,679** in 2024—the decade high; **3,487** in 2025, down 5.2% but still the second-highest in eight years (Sedgwick, 2025; Sedgwick, 2026).

The key evidence outlined above raise questions about whether such a rigorous MDR framework effectively ensures patient safety and why there is a significant difference in perception between stakeholder groups regarding the MDR role in protecting patient and user health. This observed difference between regulatory compliance, actual safety outcomes, and stakeholder perceptions highlights the importance of investigating the effectiveness of the MDR and its dynamics.

AIM: Critically evaluate whether MDR compliance diverges from real-world device-safety outcomes and stakeholder expectations.

OBJECTIVES
- To examine whether the MDR framework enables elements of ineffective regulatory oversight.
- To identify and analyse the MDR elements that may contribute to the ineffective regulatory oversight.
- To assess the implications of maintaining ineffective regulatory practices.
- To investigate the relationship between regulatory practices, real-world safety outcomes, and stakeholder perceptions.

HYPOTHESIS: Hypothesis: MDR compliance does not translate into meaningful safety oversight that reflects real-world performance.

Methodology / Methods

Research Design

Research Philosophy: Pragmatism

Research Approach: Deductive

Methodological Choice: Mono-method quantitve + limited qualitative input

Strategy: Survey questionnaire

Time Horizon: Cross-sectional

Data Collection and Sample Size

Participants: MDR professionals working with Class IIa, Class IIb and Class III
- Regulatory Affairs
- Quality Assurance
- Clinical Research and Evaluation
- Manufacturing/Production
- MDR Vilgilance/Post Market Surveilance
- Research & Development

Sampling Method: Non-probability purposive sampling

Distribution: LinkedIn

Survey: 18 questions (likert-scale + multiple choice+dichotomous)

Required Sample Size: 385 responses (MOE ±5%; 95%CL)

Collected Sample Size: 74 responses (MOE ±11.4%; 95%CL)

Data Analysis

Metthods Used: Descriptive Statistics; Correlation Analysis; t-tests/ ANOVA

Purrpose: Patterns; Regulatory Effectiveness; Stakeholder Perspective

Ethical Considerations and approval

- This study was completed in accordance with Griffith College's ethics policy, which also included informed consent, voluntary participation, confidentiality, anonymity, and protection from harm.
- All participants were provided with clear information, including the research purpose, what participation involves, and their right to withdraw at any time before submitting the survey.

Results

Stakeholder Perceptions of EU MDR Effectiveness

Figure 1 shows the distribution of responses regarding respondent confidence in EU MDR-approved device safety and effectiveness(1), perceptions of regulation functioning more as a checklist or documentation exercise than as a meaningful safety process(2), perceptions of MDR compliance ensuring safety and effectiveness in real life(3), perceptions of the MDR providing effective oversight for higher risk(Class IIb and Class III) devices(4), perceptions of false sense of safety that medical device regulation may create for patients, clinicians, and manufacturers(5), and perceptions of regulatory systems that can the appearance of oversight without ensuring real-world safety(6).

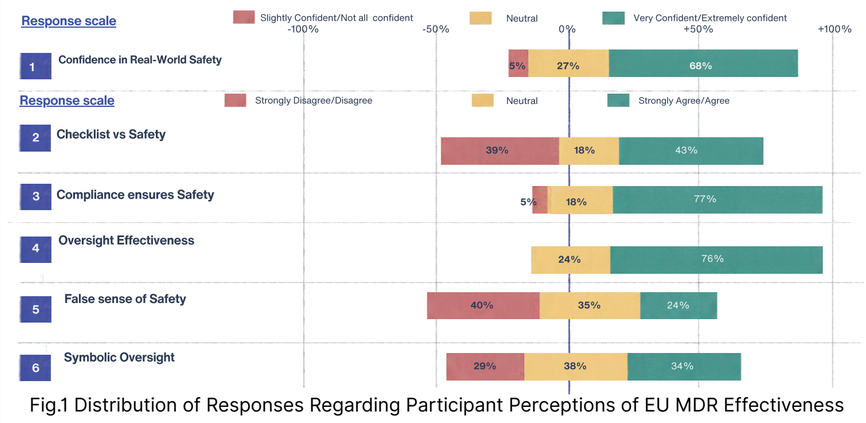


Fig.1 Distribution of Responses Regarding Participant Perceptions of EU MDR Effectiveness

Factors Contributing to Ineffective or Symbolic MDR Oversight

Stakeholders reported that the top factors contributing to ineffective or symbolic MDR oversight include ambiguity in regulatory requirements, reliance on manufacturer-generated evidence, and limited clinical evidence or equivalence pathways. Additional factors cited were competition between notified bodies, political or economic pressures, and limited regulatory capacity. Ref. Fig. 2 for responses distribution.

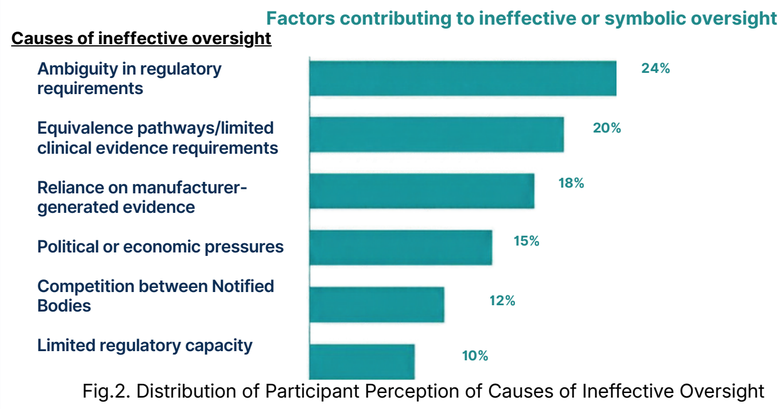


Fig.2. Distribution of Participant Perception of Causes of Ineffective Oversight

Key Areas for Safety Oversight Improvement

Stakeholders identified the top improvements for a more meaningful safety oversight under the MDR listed in the Figure 3 below.



**Includes: certification costs and innovative approaches such as simulated clinical data.*

Fig.3. Distribution of Participant Suggested Improvements

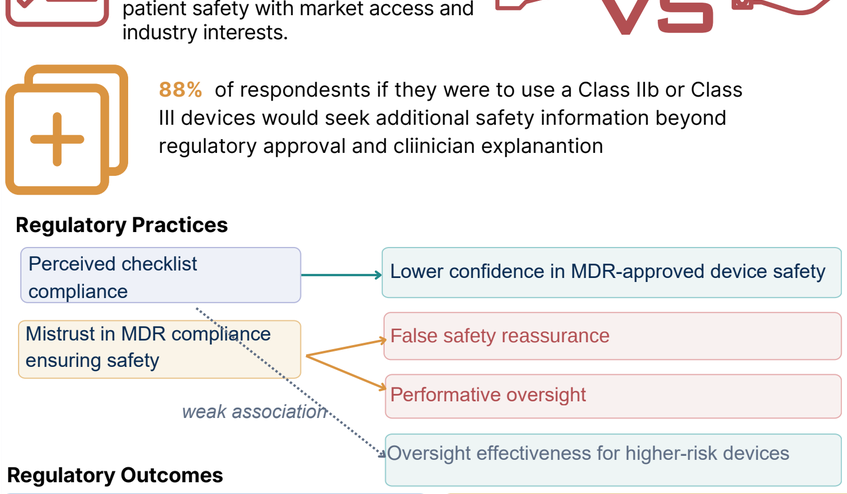
Audits/Certification Primary Function and Regulatory Priorities

47% of respondents reported that audits and certification primarily ensures compliance, and **43%** of respondents perceived the medical device approval process as balancing patient safety with market access and industry interests.



88% of respondesnts if they were to use a Class IIb or Class III devices would seek additional safety information beyond regulatory approval and cliinician explanantion

Regulatory Practices



Regulatory Outcomes

No unsafe or recalled device experience		Unsafe or recalled device experience	
Confidence in MDR-approved safety	no significant difference	Confidence in MDR-approved safety	not significantly lower
False safety reassurance	lower perception	False safety reassurance	**higher perception**
Performative oversight	lower perception	Performative oversight	**higher perception**

Discussion

Table of Findings

Finding area	Key finding	Interpretation/Implication
Confidence in MDR-approved devices, compliance and oversight	Moderately high confidence. Higher confidence in compliance than in real world-safety	System is generally viewed as functioning adequately. Compliance may not reflect real-world safety.
Checklist compliance	More people viewed compliance as documentation than as meaningful real-world safety.	Compliance-based regulation may not fully reflect meaningful, outcome-driven safety oversight. Potential gap between formal compliance and substantive safety outcomes.
False sense of safety and Performative Oversight	Mixed views on approval creating false safety or performative oversight.	Stakeholders are neither fully confident nor fully critical of the regulatory system. Regulatory compliance does not consistently ensure real-world safety.
Audits and certification primary function	Almost half saw audits as ensuring compliance, not real-world safety.	Compliance-driven oversight. System design and operational factors may contribute to a gap between regulatory compliance and meaningful safety oversight.
Regulatory Priorities	Many respondents perceived the regulatory system as balancing patient safety, market access, and industry interests.	Regulatory decisions or outcomes are perceived as inflluenced by factors beyond safety. Concerns over ecocomic pressures influencing safety decisions. Competing priorities may dilute safety focus.
Causes of ineffective oversight and improvements	Ambiguous rules; manufacturer evidence; weak clinical evidence; notified-body competition; political/economic pressure; limited capacity. Top improvements: post-market oversight, clinical-evidence standards, safety-data transparency.	Structural and procedural weaknesses drive limitations. Gaps in real-world monitoring, evidence requirements, and transparency MDR limitations stem not only from compliance failures but also from underlying structural and procedural mechanisms.
Regulatory Practices	Perception of checklist compliance linked to lower safety confidence; Mistrust linked to false reassurance. and performative oversight. Perception of checklist compliance not linked to lower perceptions of oversight	The system combines functional effectiveness with procedural and performative elements. Compliance may overlook practical safety consequences.
Regulatory Outcomes	Unsafe/recalled-device experience increases perceptions of false reassurance, but not lower safety confidence. Most respondents would seek additional safety information.	Real-world experience increases awareness of potential regulatory limitations. Divide between regulatory compliance, perceived safety, and stakeholder behaviour. Regulatory approval may be insufficient to assess device safety.

The Main Differences Between Findings and Literature

Perceived Effectiveness of MDR: In a previously completed European Commission survey on MDR effectiveness, only 34% of economic operators perceived MDR as effective in protecting health, which is much lower than in this research, where 68% of stakeholders reported confidence in EU MDR-approved device safety, and 77% reported compliance ensuring safety.
Regulatory Oversight: The literature presents MDR as a robust, risk-based system, but respondents in this research perceived it as partly checklist-based.
False Sense of Safety: Although largely absent from the literature, findings show that experience with unsafe devices significantly increases perceptions of false safety, introducing a behavioural dimension.
Post-Market Surveillance and Transparency: The literature showed improvements in transparency and in the overall surveillance and oversight process, but stakeholders identified stronger post-market surveillance as a key unmet need, highlighting gaps in real-world monitoring
Role of Notified Bodies: The literature identified issues with notified bodies and their conflicts of interest; however, stakeholders reported competition among notified bodies as a cause of ineffective oversight least often.
Symbolic / Procedural Compliance: Although the literature discussed symbolic or procedural compliance primarily in theory, this study found empirical support for the concept in stakeholder perceptions.

Conclusion

Regulatory oversight is not perceived as wholly ineffective, but as a system that combines functional effectiveness with procedural and performative elements.
Structural and procedural factors were identified as key drivers of ineffective oversight.
Potential Implications of ineffective regulatory practices, such as inconsistent oversight, overlooking practical safety consequences, delayed detection of safety issues, and perceptions of regulatory compliance that provide false reassurance, were observed, all indicating that regulatory compliance may not fully align with perceptions of meaningful protection.
Overall, this study demonstrates that while MDR provides a structured regulatory framework, stakeholder perceptions highlight important limitations in its ability to consistently ensure real-world safety, underscoring the need for more transparent, outcome-focused, and adaptive regulatory approaches.

Recommendations

Recommendations for industry application

Strengthening post-market and outcome-focused auditing	Clarify evidence standards and strengthen capacity.	Improve transparency and outcome-based assurance	Independent manufacturer - generated data reviews	Encourage going above compliance requirements and stronger accountability systems

Recommendations for future research

Increase of Scope	Sample Size	Actual Outcomes	Specified Focus
Countries Stakeholders Time	Larger sample size	Safety data Failure reasons	Post-Market monitoring Symbolic Oversigh

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