

MDR/IVDR simplification proposal provides a more proportionate approach to life cycle oversight

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Europe requires efficient, innovation-friendly, and well-governed regulations to ensure safe and effective medical technologies for patients and health systems. Effective healthcare delivery is vital for Europe's prosperity and the competitiveness of its medical technology industry, which supplies essential devices in Europe and globally.

The In Vitro Diagnostic Medical Devices Regulation (IVDR) and Medical Devices Regulation (MDR) represented an important step forward in strengthening patient safety. However, the lack of predictability, process inefficiencies and increased administrative burden are currently reducing device availability and hindering the sector's competitiveness, especially for SMEs. The regulations have increased costs and complexity, particularly around life cycle assessment. By the end of five years, IVD manufacturers will spend at least 70% more and MD manufacturers 50% more on maintenance and re-certification compared to previous directives¹. Serious incident reports have risen by over 20%, while corrective actions increased by only 1%, indicating that more reporting has not translated into improved device safety. This has not led to proportionally more corrective actions, suggesting redundancy².

The European Commission's proposal to amend MDR and IVDR, published on 16 December 2025, offers a chance to improve the efficiency and sustainability of the EU's regulatory system. This paper sets out how the proposed oversight and reporting changes deliver a stronger, more proportionate regulatory system, with patient safety kept constant throughout. It focuses on the oversight and reporting dimensions of the proposal and complements the wider debate on delivering the Commission's simplification objectives.

Strengthening the regulatory system with smarter oversight

Even with every simplification measure in place, Europe will keep a stringent pre- and post-market system, comparable to other major jurisdictions.

The simplification proposal strengthens current regulatory oversight mechanisms by ensuring that focus and attention is concentrated where it matters most. By removing duplication and low-value administrative processes, the revision proposal frees up capacity to detect safety signals earlier, scrutinise high-risk products and areas requiring improved compliance more closely, and intervene more effectively to protect patients.

This approach delivers more targeted and effective regulation, while enabling safe and innovative devices to reach EU patients.

The revision proposal shifts MDR/IVDR to a **more risk-based, targeted approach**:

- **Targeted safety oversight for earlier intervention:** the revision proposal maintains the core oversight while making the mechanisms more targeted like periodic certificate reviews (replacing recertification), annual surveillance, pre-approval of device changes, continuous reporting (including risk-based updates to periodic safety reports and summary of safety and performance), targeted technical documentation review, as well as representative device assessment.

This means that Notified Bodies can adapt their quality management system auditing methods, tailor their scrutiny based on risk (e.g. through unannounced audits), compliance history, and post-market signals, ensuring focused scrutiny on quality systems with poor compliance. When the oversight is targeted at the areas that need improvement it can help catch issues earlier and intervene more quickly before issues escalate.

- **Resources are directed to safety signals:** By replacing duplicative processes, such as routine technical documentation sampling and fixed re-certification cycles, with a more efficient risk-based method, the proposal reduces administrative burden and frees up capacity. This allows regulators and Notified Bodies to focus on meaningful surveillance of safety data, post-market signals, and devices where concerns actually exist, rather than on repetitive, low-value administrative tasks across all devices, irrespective of their risk, establishment level and history on the market.

¹ MedTech Europe 2024 [Regulatory Survey](#): key findings and insights

² While serious incident reports increased by 20% (reporting is done on potential serious incidents), corrective actions rose by only 1%, showing that more reporting does not automatically lead to a need for action and safer products.

- **Authorities can act more quickly and effectively when issues arise:** Greater flexibility in audits and oversight, including risk-based surveillance, remote audits, transparency through EUDAMED and targeted unannounced audits, enables lean, resource-friendly and more proportionate oversight. Clearer processes, structured dialogue with notified bodies, and better integration of post-market surveillance data further support more timely and effective decision-making.
- The proposal maintains the core role and objectives of Notified Bodies' activities while changing the frequency of some Notified Body tasks to make them less redundant and more risk based.

Competent authorities remain responsible for market oversight, vigilance, and enforcement: they monitor safety issues at system level, assess serious incidents and trends, coordinate responses, and take enforcement action where needed. Through tools such as unique device identification (UDI) and the European Database on Medical Devices (EUDAMED), they benefit from enhanced traceability and transparency, enabling faster and more coordinated intervention. These responsibilities are unchanged, and new provisions are proposed to strengthen market surveillance through a Europe-wide coordination mechanism and provision of expert groups to support assessment by Competent Authorities.

Notified Bodies and competent authorities retain all oversight tools, including unannounced audits, and can also deploy them where they are genuinely needed. This concentrates qualified resources on the controls that catch real risks, rather than on routine tasks that add little to patient safety. It allows for **focused, timely detection of risks and more effective usage of qualified resources.**

Continuous life cycle assessment: foundations of the system stay solid

The MDR/IVDR introduced a life cycle based system that treats safety and performance as an **ongoing regulatory outcome rather than a one-time market access decision.** The European Commission's proposal **preserves the core principles and architecture that ensure a robust life cycle assessment:**

- **Manufacturers remain responsible for the safety and performance of their devices across the entire product life cycle from design to real-world use:** through continuous monitoring, verification, validation, post-market surveillance, trending, preventive, corrective actions, continuous design improvement, and risk management. This is supported by robust quality and risk management principles, among others, via compliance with international standards used widely across the industry (such as those for quality control and risk management). These mechanisms make safety and performance a core part of every process throughout the entire device life cycle. The MDR and IVDR revision proposal builds on these obligations rather than altering them.
- **Notified Bodies maintain their oversight role as independent and competent entities through conformity assessment and surveillance:** Notified Bodies verify compliance before and after placing on the market by assessing technical documentation, auditing manufacturers' quality systems including but not limited to their post-market surveillance system. Their oversight ensures that life cycle controls, including risk management principles, continuous state of the art consideration and post-market surveillance and vigilance-processes/measures, are effectively implemented and maintained.

Conclusion

The European Commission's proposed changes aim to reduce duplication and improve regulatory efficiency, while maintaining robust oversight for patient health and safety. The proposal sharpens the system by directing oversight to where risk actually sits, while manufacturer responsibility, Notified Bodies' independent assessments, and competent authorities' enforcement remain firmly in place.

The proposal enhances safeguards through a more targeted, risk-based approach, removing unnecessary administrative layers while preserving intervention where needed. This results in a more effective and patient-centred framework that not only maintains safety standards but also strengthens protection by focusing oversight on areas with the greatest public health impact. At the same time, by adjusting redundant reporting mechanisms, it supports a more competitive manufacturing sector which is better able to provide new and essential devices for patients and healthcare systems.

A simpler system is not a shortcut on safety. It is the condition for safety, and for a resilient healthcare system.

