

The Future of Europe's Medical Technology Regulations

MedTech Europe's vision for an efficient, innovation-focused, and well-governed regulatory framework

Executive Summary

MedTech Europe and its members fully support the objectives of the medical technology regulations, *In Vitro* Diagnostic Medical Devices Regulation 2017/746/EU (IVDR) and Medical Devices Regulation 2017/745/EU (MDR): to establish a “robust, transparent, predictable and sustainable regulatory framework for [*in vitro* diagnostic] medical devices which ensures a high level of safety and health whilst supporting innovation”.¹ However, after almost six and a half years of implementation, the IVDR and MDR have still not fully achieved these objectives.

While considerable work has been done by all stakeholders to address the short-term implementation challenges, there are structural issues in the regulatory system which make it slow, unpredictable, costly and complex, and lacking in agile pathways for innovation. These structural issues cannot be solved through the implementation of IVDR and MDR alone.

MedTech Europe is calling for comprehensive reform to make the regulations work for patients and European health systems. Reform should address the three key areas of efficiency, innovation and governance, all while maintaining the regulations' high level of device safety and performance:

- **An Efficient CE Marking System:** We need a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes.
- **A System that Works for Innovation:** We propose the inclusion of an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers.
- **An Accountable Governance Structure:** We suggest the establishment of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions.

We believe that discussion between all stakeholders must start now to realise a comprehensive reform with regards to the above three areas. At the same time we remain committed to working with all stakeholders to find short-term solutions to the implementation issues in the regulations, for example through implementing acts, guidance, best practice or other means. In this context, we urge the Medical Devices Coordination Group and stakeholders to fix issues without delay where solutions may be identified in the short-term.

Only together can we deliver on the original goals of the IVDR and MDR to develop a robust, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health while supporting innovation, for the benefit of European patients, health systems and society.

The full position paper can be found on MedTech Europe's website:

<https://www.medtecheurope.org/resource-library/the-future-of-europes-medical-technology-regulations/>

¹ See first and second preambles to IVDR and MDR. The objectives have been paraphrased.