MDR/IVDR revision: a regulatory system at a crossroads

Europe's regulatory framework for medical technologies is at a decisive moment. MedTech Europe fully supports the European Commission's objective to streamline the EU regulatory system for medical devices and in vitro diagnostics and urges Parliament and Council to bring these much-needed improvements swiftly.

The Medical Device (MDR) and *In Vitro* Diagnostics Regulations (IVDR) were designed to raise the bar for patient protection and strengthen trust in medical technologies. Yet nearly a decade into implementation, the very goals these regulations were meant to achieve are being undermined by structural shortcomings: slow and unpredictable conformity assessment timelines, disproportionate and costly administrative burdens, and inconsistent interpretation across Member States.

The cost of delay in addressing the system's shortcomings is concrete and cumulative. Companies are already redirecting investment away from Europe, patients face avoidable disruptions to the technologies they depend on, and the EU falls further behind competing jurisdictions. The window to act is now.

In vitro diagnostics deserve equal attention in this process. IVDs play a critical role in health systems: they inform diagnosis, guide treatment decisions and underpin public health surveillance. Given that the rules for in vitro diagnostics are being proposed for revision in the same proposal as for medical devices, it is imperative that the co-legislators do not lose focus on the amendments to the In Vitro Diagnostic Regulation which will determine how Europe will ensure access to key diagnostic technologies for decades to come.

MedTech Europe's assessment is structured around three tiers:

- **WELCOME** the core direction on simplification and international cooperation: measures that, if preserved and reinforced, will make a tangible difference for patients and industry alike.
- **STRENGTHEN** several provisions where the proposal's ambition risks being undermined by implementation gaps: including making innovation pathways more fit-for-purpose, ensuring timely integration of AI requirements, and avoiding unintended red tape for IVD performance studies.
- **RETHINK** the approach to reprocessing of single-use devices, where the proposed "reusable by default" presumption adds unclear administrative burden and departs from established safety principles.

WELCOME: what the proposal gets right

Simplification

Nearly nine years of MDR and IVDR implementation have exposed structural shortcomings, but have also given regulators the practical experience to understand how the system can work more efficiently without compromising safety. Key measures MedTech Europe strongly supports:

- **Open-validity certificates with periodic risk-based reviews**: removing fixed five-year recertification cycles eliminates an artificial bottleneck while maintaining ongoing oversight proportionate to the device's risk profile.
- **Streamlined change control**: clearer distinction between product changes manufacturers can implement without prior notification and those requiring approval.
- **Risk-based sampling in conformity assessment**: proportionate scrutiny for lower and medium-risk devices removes duplicative procedural steps.
- **Broader recognition of clinical evidence**: explicit recognition of well-established technologies, and acceptance of non-clinical evidence including modelling and simulation.
- **Proportionate treatment of near-patient IVD tests**: aligning the regulatory pathway for near-patient tests with other professional-use diagnostics.
- **Digitalisation**: electronic submission of technical files, digital EU declarations of conformity, digital labelling and digital provision of information to healthcare professionals and patients.

Even with all simplification measures in place, Europe will retain a stringent pre- and post-market regulatory system comparable with other major jurisdictions.

What is medical technology?

Medical technologies are products, services or solutions used to save and improve people's lives. In their many forms, they are with you from prevention to diagnosis and cure. There are three main categories of medical technologies:

Medical Devices (MDs)

Are products, services or solutions that prevent, diagnose, monitor, treat and care for people.

In vitro diagnostics (IVDs)

Are non-invasive tests used on biological samples (for example, blood, urine or tissues) to determine the status of a person's health.

Digital health

Are tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of a person's health and lifestyle.

International cooperation

Medical technologies are developed, manufactured and used on a global scale. Effective cooperation between regulatory systems of comparable stringency reduces duplication, lowers costs and accelerates patient access without compromising safety. The Medical Devices Single Audit Programme (MDSAP) allows a single quality management system audit to satisfy the requirements of multiple jurisdictions. Strengthening cooperation also enhances the international recognition of the CE mark, making it easier for EU-based companies, particularly SMEs, to access new markets.

STRENGTHEN: targeted improvements needed

The Commission's proposal rightly addresses many structural challenges. In several areas, however, the legislative text does not yet fully deliver on the proposal's own stated ambition. MedTech Europe proposes targeted improvements to ensure it delivers in practice what it promises on paper.

Innovation: breakthrough and orphan pathways

The proposed breakthrough and orphan device pathways need refinement in two areas to realise their full potential:

- **Paediatric inclusion**: paediatric devices should be explicitly included in the scope of Article 52a MDR, ensuring that all children benefit from adapted assessment pathways.
- **Orphan device threshold alignment**: the proposed IVDR threshold of 1 in 12,000 individuals per year risks excluding diagnostics for rare conditions. Aligning the definition with the established European threshold for rare diseases (5 in 10,000) also would ensure needed coherence with the orphan medicinal product framework.

Cybersecurity reporting

Two distinct cybersecurity scenarios require different regulatory responses: patient safety incidents should follow established vigilance reporting channels, while vulnerability disclosures must allow manufacturers time to develop patches before disclosure.

AI integration

Integrating AI Act requirements into a single MDR/IVDR conformity assessment process is the right approach. To bring legal clarity, a time-bound process to operationalise this integration should be included in the legislation.

Blood draws in performance studies

Routine blood draws and finger-pricks are safe, well-established procedures. Yet under the current framework, they are treated as having the same risk as biopsies or spinal taps. MedTech Europe proposes amending Article 58(1) IVDR to clarify that full authorisation requirements are triggered only where the invasive procedure poses a major clinical risk to subjects.

RETHINK: reprocessing of single-use devices

The Commission's proposal shifts the regulatory default: devices will be presumed reusable unless manufacturers justify a single-use designation. This is a departure from the current MDR framework and from every other major jurisdiction.

The Commission's own 2024 study highlights major evidence gaps regarding safety and effectiveness of reprocessing. MedTech Europe's position:

- Reprocessing should not be the regulatory default. Single-use devices are specifically engineered for single use, and that design choice is integral to their safety profile.
- The proposal should be rebalanced to remove the burden on manufacturers to justify that devices which are single-use only cannot be reused.
- Where single-use devices are refurbished, MedTech Europe supports clear assignment of full manufacturer responsibilities to the refurbisher.

The MedTech Europe/BCG report shows there is no "one-size-fits-all" approach to circularity in healthcare. Reprocessing may be one option depending on the product, but not the default solution.

Conclusion

The Commission's proposal provides a solid basis for reform. With targeted refinements on predictability, proportionality and support for innovation, the EU can build a regulatory framework that gets safe technologies to patients faster, strengthens health systems and restores Europe's position as the destination of choice for medical technology development.

A simpler, more predictable system is not a shortcut on safety. It is the condition for safety, for patient access, and for Europe's long-term competitiveness.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions. www.medtecheurope.org

For more information, please contact: publicaffairs@medtecheurope.org

MedTech Europe
from diagnosis to cure