

Towards a Single Regulatory Pathway for AI-Enabled Medical Technologies

We, the undersigned organisations representing healthcare professionals, researchers, innovators and industry across Europe, recognise the growing role that artificial intelligence (AI) can play in improving patient care and supporting the sustainability of healthcare systems.

As Europe faces ageing populations, growing workforce shortages and rising healthcare demand, AI-enabled medical devices and diagnostics can help support earlier diagnosis, more personalised treatment, improved clinical decision-making and more efficient care delivery. When appropriately designed, clinically validated, including by involving clinicians in their development, and responsibly deployed, AI can provide valuable support to patients and healthcare professionals across screening, medical imaging, laboratory medicine and patient monitoring¹ by identifying clinically relevant patterns, improving workflows and supporting more timely and informed clinical decisions. AI-enabled medical technologies should function reliably and be user-friendly in clinical work environments, so that they support rather than hamper clinical workflows. Realising these benefits, however, requires public and professional trust and a regulatory framework that is both safe and workable, enabling timely access to innovative healthcare technologies.

Recent experience with the implementation of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) demonstrates the consequences of regulatory complexity. While the Regulations have introduced a stronger regulatory framework, including enhanced safety, clinical evidence, lifecycle oversight and transparency, certification timelines have doubled, increasing from 9–12 months to 12–24 months, while predictability of regulatory processes has been reduced, contributing to delays in patient access, product withdrawals and shortages.

¹ European Commission: Directorate-General for Health and Food Safety, PwC, EEIG and Open Evidence, [Directorate-General for Health and Food Safety, PwC, EEIG, Open Evidence], *Study on the deployment of AI in healthcare – Final report*, Publications Office of the European Union, 2025, <https://data.europa.eu/doi/10.2875/2169577>

Today, **more than 60% of healthcare professionals report medical device shortages**, while a similar proportion of hospital pharmacists indicate that shortages have delayed patient care^{2 3}.

The current revision of the MDR/IVDR provides a critical opportunity to avoid creating two parallel product-regulatory systems with overlapping and divergent requirements for AI-enabled medical devices and diagnostics.

Medical devices and diagnostics represent a highly regulated sector where AI-related risks must be assessed alongside clinical benefits, safety and performance throughout the product lifecycle. **A tailored sector-specific framework, provided by the MDR/IVDR, is therefore the most suitable to ensure that AI-enabled medical technologies can be assessed in their full clinical context**, rather than treating AI as an isolated and separate component of a product.

In its proposal for the revision of the MDR/IVDR, the European Commission proposed to provide one single clear framework for AI-enabled medical devices (by moving MDR and IVDR from Section A to Section B of Annex I of the AI Act and providing means for applying AI-relevant requirements through MDR/IVDR). This reflects the fact that medical devices and diagnostics are already subject to comprehensive sector-specific legislation requiring manufacturers to continuously demonstrate and maintain, safety, performance, clinical and performance evaluation, risk management, vigilance and post-market surveillance and lifecycle oversight. The Commission's proposal also recognises that **highly regulated sectors may require tailored approach**. Medical devices and diagnostics represent precisely such a sector.

Integrating the relevant AI Act requirements, such as **transparency, data governance and human oversight** into the MDR and IVDR would ensure that these technologies continue to be assessed through **one coherent regulatory pathway while maintaining the objectives and requirements of the AI Act**, including high standards for patient safety, AI governance, equity and appropriate human and clinical oversight. This approach would allow the safety and performance of an AI-enabled medical technology to be assessed as a whole and in its full clinical context, rather than separating the assessment of its AI component from that of the medical device or diagnostic of which it forms an integral part. It would also allow post-market safety signals and incidents affecting patient safety to be addressed through a unified system of vigilance and market surveillance fundamental for faster and appropriate action.

In doing so, it would preserve the safeguards and requirements applicable to high-risk AI systems while avoiding duplicative regulatory processes and providing greater legal

² https://www.medtecheurope.org/wp-content/uploads/2025/03/250318_mte-report-on-admin-burden-ivdr_mdr_final.pdf?utm_source=chatgpt.com

³ <https://eahp.eu/policy-hub/medical-device-regulation/>

certainty for all stakeholders. It would also accelerate patient access to innovative devices, reinforce Europe's competitiveness, and make the EU a more attractive environment for development and deployment of innovative, regulated AI-enabled medical technologies that improve patient outcomes.

To make this framework comprehensive and operational, **the revised MDR and IVDR should require the European Commission to adopt without undue delay, the necessary measures reflecting the relevant high-risk AI requirements in the General Safety and Performance Requirements of the MDR and IVDR.** These measures should be developed transparently and in consultation with patients, healthcare professionals, including clinicians, scientific experts and other relevant stakeholders.

We therefore call on the European Parliament and the Council to preserve the Commission's proposal of moving the MDR and IVDR from Section A to Section B of Annex I of the AI Act and reflecting relevant AI-Act high-risk requirements into the MDR/IVDR in a time-bound process. Europe's **ambition should be clear: to create a regulatory framework that protects patients, supports healthcare professionals, enables research and innovation, and ensures that Europeans can benefit from the safe and timely deployment of AI-enabled healthcare technologies.**

