To: European Commission, DG SANTE
Attn.: European Commissioner for Health and Animal Welfare, Olivér Várhelyi
Rue de la Loi 200
1040 Brussels
Belgium

Brussels, 19 September 2025

Subject: Medical technologies in Europe – Outlook for 2025 and beyond, and measures needed to safeguard availability and innovation

Dear Commissioner Olivér Várhelyi,

We thank you for your decisive leadership and swift action to improve Europe's rules for medical devices and in vitro diagnostic (IVD) medical devices by the end of 2025.

With the revision process confirmed for the end of 2025, we would like to outline our reflections on what will be essential for that revision and which measures are required in parallel. Bringing in both short-term relief measures and a sustainable, well-structured, well-governed and well-resourced regulatory framework, will ensure European citizens and health systems continue to benefit from safe and effective medical technologies.

We are mindful of the significant work and coordination your medical technology unit is leading with stakeholders to improve the regulatory system. Given the immense strain on Europe's medical technology sector, much is at stake to ensure that a 'full range' of existing and innovative devices are consistently available to Europe's patients. The global competitiveness of Europe's regulatory pathway for medical technologies must be significantly improved to ensure patients benefit from continued availability of medtech products, by considerably reducing high life cycle cost and other unintended effects of the medical technology regulations.

Different kinds of actions are needed to provide short-term relief while laying the reform foundation for a fully functioning regulatory system:

1. We strongly welcome the announced legislative reform to revise the rules for medical technologies, provided it delivers a regulatory system that is efficient, innovation-friendly, adaptable and well governed.

a. This reform should amend both the Medical Devices Regulation and IVD Regulation[1], taking into account the specificity of each sector.

b. The Notified Body system is essential and should operate as a core pillar of the future regulatory framework. Notified Bodies should be overseen by a single and accountable governance structure which also ensures both the efficient functioning and the global competitiveness of the EU CE-marking system.

2. Urgent (short term) relief measures are needed in parallel to a revision proposal by the end of 2025 or early 2026.

a. An implementing act that harmonises rules for notified bodies is needed. It should set maximum notified body assessment timelines, define the scope of changes to be notified, remove duplication of vigilance review, enable early dialogues with manufacturers which set clinical expectations and mitigate the burden of re-certification.

b. Plans by the European Commission to run pilots on regulatory pathways for orphan & paediatric devices and breakthrough innovations should be set into motion. Expediated regulatory pathways also should be built into the revision proposal to ensure lasting benefits and continued investment in cutting-edge technologies.

1) EU Regulations 2017/745 and 746

c. A targeted postponement of re-certification requirements for devices already certified under the medical technology regulations is needed now to avoid a new major bottleneck for devices transitioning to medical devices rules by 2028, and to keep devices available.

In addition to the above actions, we urge you to ask Ministers of Health at the upcoming EPSCO meeting on 2 December, to more substantially and sustainably invest in the governance and resourcing (both operational and science-based) of the medical technologies regulatory system – both today and once it is reformed. In their letter of June 2025, the Heads of Medicines Agencies and Competent Authorities have stated, "Strategic investments in the regulatory system will lead to long-term savings and a simple, clear and well-functioning regulatory system for the benefit of patients and the regulated sector." This message reflects what is needed to secure the future of medical technologies in Europe.

Our industry stands ready to collaborate with the European Commission to deliver practical solutions that secure faster and continued access to safe and effective medical technologies, strengthen Europe's health systems, embrace digitalisation and foster trust in a future-ready regulatory framework that works for patients and innovators alike. By acting together now, Europe can ensure that the IVDR and MDR deliver on their promise: safeguarding patients enabling the EU medtech industry to grow, deliver innovations and sustain delivery of products while upholding the highest standards of safety and performance.

Yours sincerely,