Dear Members of the European Parliament,
Dear Representatives of Member States in Telecommunications and Information Society Working Party
Dear Executive Vice-President Virkkunen,
Dear Commissioner McGrath,

Brussels, 10 March 2026

CPME and HOPE
Open letter to safeguard safe, transparent, and accountable AI for Medical Devices and In Vitro Medical Devices

Doctors and hospitals and healthcare services call on EU legislators to maintain medical devices (MD) and *in vitro* medical devices (IVMD) within the scope of the AI Act, and to apply the requirements for high-risk AI systems set out in Chapter III, Section 2 of the AI Act.

While the MDR and the IVDR ensure general medical safety and performance, these regulations were not designed for adaptive, data-driven systems. Maintaining AI used for medical purposes within the scope of the AI Act is essential to ensure harmonised, transparent, and future-proof regulatory oversight of AI-specific risks, while fully preserving the integrity and primacy of the MDR and IVDR. It will also warrant trust, leading the way for a better uptake of AI medical devices in the healthcare sector.

Therefore the undersigned urge to maintain MD and IVMD under the AI Act due to the following reasons:

The AI Act improves clarity and consistency of AI-specific expectations. It explicitly delineates what notified bodies should look at to certify high-risk AI device, ensuring a harmonised and safer approach. It brings legal certainty for manufacturers on what requirements are analysed and how by notified bodies, and for deployers of AI systems in healthcare who also bear responsibilities for high-risk applications. The AI Act further ensures consistent application across the EU, avoiding Member States legislating in this area. Without this legal framework, capacities to certify AI medical devices remain dependent on individual implementation choices at the level of notified bodies.

The AI Act regulates AI-specific risks which are not explicitly addressed in the medical devices' regulations. The AI Act complements the MDR[1] and the IVDR[2] by introducing requirements to address hazards and risks for health, safety and fundamental rights specific to AI systems.[3] For example, risks related

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
[3] See in this sense the Guidance endorsed by the Artificial Intelligence Board (AIB) and the Medical Device Coordination Group (MDCG) on the 'Interplay between the Medical Devices Regulation (MDR) & In vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA)' AIB 2025-1 / MDCG 2025-6, <https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en>accessed 2 March 2026, June 2025, p 2.

to machine learning, bias mitigation, model performance degradation, data representativeness, data training and validation, thus, to avoid unsafe clinical decisions. It should also be noted that several AI tools, such as LLM, can be constantly trained, tuned and influenced by prompting. This is different than the production of a drug or an industrial process of a medical device that is deterministic and reproducible.

The AI Act requirements integrate into existing procedures for AI medical devices. The requirements in Chapter III, Section 2 of the AI Act integrate into the medical devices' conformity assessment. Pursuant to Article 8(2) of the AI Act, the notified bodies of medical devices would be the same as those for high-risk AI. The guidance which has been published on the interplay between the Medical Devices Regulation clarifies and supports manufacturers while maintaining safety standards.[4]

The AI Act ensures minimum dataset governance standards. The training of datasets in healthcare must be carried out on validated datasets specifically tailored to healthcare. Using non-validated content can lead to incorrect information in clinical decision-making system process. Product manufacturers should be transparent about the technology used and the underlying training data, as required by the AI Act. In addition, machine-to-machine communication, the agentic architecture, and automated retrieval of information are novel aspects not addressed in the MDR and the IVDR, since the AI Act is the EU regulation conceived to address these future risks.

The AI Act improves trust in AI medical devices. Trust is essential for the adoption and uptake of AI in healthcare. If the wide AI product offer available on the market is not duly certified, the result will continue to be the slow uptake of AI in the sector. The explicit AI governance in the AI Act improves human oversight, AI system transparency mechanisms, as well as explainability and interpretability, which are most important for the AI deployer. To generate trust, notified bodies should be able to evaluate human oversight design, the quality of datasets, the AI model validation methodology, the AI performance monitoring plan, and the automatic logging requirements which can be relevant for liability discussions.

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*The **Standing Committee of European Doctors** (CPME) is a European not-for-profit association representing 36 national medical associations across Europe, giving voice to over 1.7 million doctors.*

*The **European Hospital and Healthcare Federation** (HOPE) is a European not-for profit association representing 37 national public and private hospital and healthcare associations and hospital, health and social care services owners.*

Resources:

CPME: Feedback to Digital Omnibus Package - Calling for credibility of digital regulations in Europe, February 2026, and Deployment of AI in healthcare: Sector-specific challenges and accelerators, November 2024.

HOPE: HOPE Position on the European Action Plan on the cybersecurity of hospitals and healthcare providers, June 2025, and HOPE contribution to the European Commission Call for Evidence "Digital Fitness Check", February 2026

[4] Ibid.