Ms Henna Virkkunen
Executive Vice-President
Tech Sovereignty, Security and
Democracy European Commission

BEUC-L-2026-097 15 July 2026

Subject: The AI Act must keep regulating AI-embedded medical devices

Dear Executive Vice-President Virkkunen,

Ensuring the safety of AI-embedded medical devices is a matter of patient safety, consumer protection and public trust in healthcare. We, the undersigned, organisations representing standardisation, consumers, digital rights, doctors, pharmacists and hospitals, express our serious concerns regarding the European Commission's proposal to exclude medical devices and in vitro diagnostics from the scope of the AI Act. This change, part of the Medical Devices (MDR) and the In Vitro Diagnostic Medical Devices Regulations'(IVDR) revision, is an unacceptable rollback. It strips AI-embedded medical devices of the core horizontal safeguards mandatory for high-risk AI systems, at the expense of patient safety and consumer protection.

We therefore strongly call on co-legislators to retain these devices within the full scope of the AI Act and to prevent regulatory gaps. Only this way can the EU ensure consumer safety and harmonised, robust oversight of AI-specific risks and harms in healthcare.

Our call:

- **Keep MDR and IVDR in Section A of Annex I of the AI Act** by deleting Article 1, Point (5)(b) (amending the MDR), Article 2, Point (5)(b) (amending the IVDR), and Article 4 of the proposal and its corresponding Recital 23.
- **Foster effective coordination within the Commission**, notably between DG SANTE and the AI Office, to ensure the smooth implementation and robust oversight of the AI Act.
- **Support the coherent application of the two frameworks through guidance** instead of removing core consumer and patient protections.

The proposal removes consumer and patient protections, not duplication

The AI Act complements and strengthens the MDR and IVDR. The EU adopted the AI Act on a clear premise: the greater the risk an AI system poses, the stronger the protections must be. In a sector where the margin for error is measured in human lives, robust AI-specific safeguards are essential, not optional. The MDR and IVDR were not designed to regulate AI and do not offer comparable protections.

Excluding AI-embedded medical devices from the AI Act would render critical safeguards inapplicable: risk management focused on AI-specific risks; human oversight with safeguards against automation bias; training data quality and bias examination; transparency to deployers; accuracy, robustness and cybersecurity; and the protection of fundamental rights.

Consumers and patients would be left unprotected against the very risks the AI Act was adopted to address.

Implementing acts are no alternative to clear, predictable EU legislation on AI. Some of these requirements, such as deployer obligations and the fundamental rights dimension, have no basis in the medical devices' framework. Others would inevitably be watered down. This would result in legal uncertainty, fragmentation, regulatory gaps and lower safety levels for consumers and patients.

The AI Act already ensures both frameworks work seamlessly together

The problem this proposal claims to solve has already been solved, and its proposed solution would remove protections. EU co-legislators already built extensive streamlining into the AI Act to avoid administrative duplication with the medical devices framework. This includes:

- A single set of technical documentation;
- Integrated quality management and post-market monitoring obligations;
- One EU declaration of conformity;
- And serious incident-reporting linked to health through the existing MDR/IVDR vigilance system.

MDR/IVDR notified bodies can also assess AI Act conformity, with their AI competence evidenced, and the same market surveillance authorities remain in charge. The Digital Omnibus on AI went even further, allowing notified bodies to apply and be assessed only once to acquire certified AI competence in multiple areas.

Do not reopen the co-legislators' recent agreement

The interplay between the AI Act and the MDR/IVDR was extensively debated in the Digital Omnibus on AI, where the co-legislators rightly decided to keep AI-embedded medical devices within the scope of the AI Act. Reopening the question a few months after the agreement creates precisely the legal uncertainty the proposal claims to remove.

The European Parliament's Committee on Internal Market and Consumer Protection's draft opinion rightly rejects this proposal. Rather than removing protections, the focus should be on ensuring both regimes effectively work in parallel and in a mutually reinforcing manner. The AI Board and the Medical Device Coordination Group have already issued joint guidance on the coherent application of the two frameworks, demonstrating that coordination is the right path forward.

We call on the co-legislators to defend the integrity of the AI Act and to reject any attempt to erode its horizontal character or diminish the existing level of consumer protection.

This letter has also been sent to Commissioner Várhelyi, Council and European Parliament representatives.

We remain at your disposal and would welcome the opportunity to engage in further dialogue.

Yours sincerely,

The Consumer Voice in Europe