Bundesverband Medizintechnologie e.V.

Position paper

Simplification - digital package and omnibus

Necessary actions to ensure applicability of the Ai-Act for medical devices

October 2025

BVMed – the German Medical Technology Association – supports the EU's digital agenda and the European Commission's objective to foster innovation that benefits both patients and healthcare systems.

At the same time, BVMed shares the Commission's assessment that the existing regulatory framework needs to be simplified and streamlined to strengthen – rather than hinder – Europe's competitiveness.

Medical technologies are already subject to a comprehensive and mature regulatory framework under the Medical Devices Regulation (MDR). The MDR sets out strict requirements for product safety, quality and performance, and provides well-established procedures for conformity assessment – often involving a notified body – as well as harmonized standards, market surveillance by competent authorities, and post-market surveillance and vigilance obligations for manufacturers.

Any additional obligations introduced through horizontal EU legislation must therefore be aligned with, and integrated into, the existing MDR framework. Avoiding duplication and overlapping or even contradicting requirements is essential.

The majority of medical devices incorporating artificial intelligence (AI) will qualify as high-risk AI systems under Annex I, Section A of the AI Act and will need to comply with its provisions by August 2027. From BVMed perspective, however, the regulatory system under the AI Act is currently not operational, and there is a serious risk that it will not be fully functional by the end of the transition period. The implementation of the MDR has clearly demonstrated that such complex frameworks require significantly more time and that deadlines had to be extended several times.

BVMed therefore calls on the European Commission to

- **extend the current transition period by at least 24 months,**
- **urgently provide clarity on key open questions that are essential for the effective application of the AI Act and its coherent interaction with the MDR.**

Otherwise, there is a real risk that many established, safe and high-performing medical devices could disappear from the EU market due to a non-functional regulatory system – depriving European patients of access to proven medical technologies.

In the following, BVMed would like to outline several of these critical issues in more detail.

1.
Notified Body assessment

Under the MDR, 51 notified bodies are currently designated in Europe for the conformity assessment of medical devices. Almost all of these notified bodies are authorized for the existing MDR codes related to medical software (MDA 0315 = software / MDS 1009 = hardware incorporating software). They therefore possess proven expertise and experience in the conformity assessment of software used in medical devices. A portion of this software can also be considered as AI.

To avoid double regulation and further delays – and to provide planning certainty for both manufacturers and notified bodies in Europe – the European Commission and the EU Member States should urgently develop harmonized pragmatic solutions to enable MDR-designated notified bodies to also perform conformity assessments for AI-enabled medical devices.

A full new designation procedure may be required in other sectors where no third-party conformity assessment currently exists. However, this should not apply to medical devices, which have operated under a robust and well-established conformity assessment system for decades.

Notified bodies already designated under the MDR - and possessing sufficient expertise and experience with the relevant MDR codes for software - should be pragmatically designated (based on Article 29(4) of the AI Act) to assess AI-systems within medical devices.

2.
MDR as sector-specific legislation is considered lex specialis

Under the principle of lex specialis, sector-specific legislation takes precedence over more general, horizontal rules when both address the same or similar subject matter.

The MDR represents such lex specialis within the EU's regulatory framework, providing a comprehensive and detailed set of requirements for the safety, performance, and conformity assessment of medical technologies. Where horizontal legislation establishes additional or overlapping obligations, these must be integrated into the existing processes and evidence requirements of the MDR, rather than applied in parallel. This ensures legal coherence, avoids duplication, and maintains a clear, sector-specific regulatory pathway for medical devices.

During the trilogue negotiations on the AI Act, the European Parliament proposed a way to strengthen the lex specialis status of the MDR within the AI Act. This was to be achieved through the introduction of a new Article 8(2)(a), providing a legally sound mechanism to recognize the MDR as lex specialis while ensuring that AI-specific requirements not covered by the MDR would continue to apply to medical devices.

This approach would maintain legal coherence, avoid duplication, and ensure a clear, sector-specific regulatory pathway for medical technologies. The European Commission should appropriately emphasise and reaffirm the MDR's status as lex specialis within the EU legislative landscape, in order to provide regulatory certainty to all market actors and to avoid double regulation.

The European Commission should emphasize and reaffirm the MDR's status as lex specialis within the EU legislative landscape, in order to provide regulatory certainty to all market actors and to avoid double regulation, building on the European Parliament's proposal for Article 8(2)(a) as a practical and legally robust approach to anchor the lex specialis status of the MDR within the AI Act.

3.
Clear legal avenue to perform pre-market clinical testing

Under the MDR, medical devices undergo clinical evaluation – and, in many cases, clinical investigations – to demonstrate conformity with the Regulation. During such clinical investigations medical devices are used on patients as so-called investigational devices (as defined in Article 2(46) MDR) without bearing the CE-mark and without being considered as placed on the market within the meaning of the MDR.

The AI Act, however, does not recognize the concept of investigational devices. It applies only to AI systems that are placed on the market according to the AI act (Article 2(1)(a)), while it explicitly excludes research, testing and development activities (Article 2(8)).

From BVMed perspective, it therefore remains unclear how this conflict can be resolved in practice. The European Commission's recommendation in MDCG 2025-6 *"FAQ on the Interplay between the Medical Devices Regulation (MDR) & In Vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA)"* (June 2025) does not, in our view, sufficiently address this issue.

A legally sound clarification is necessary confirming that, as for all other medical devices, clinical investigations for AI-enabled medical devices are governed by the MDR, allowing such products to be used as investigational devices in clinical investigations for the purpose of demonstrating conformity.

BVMed
Bundesverband Medizintechnologie e.V.
German Medical Technology Association
Georgenstraße 25, 10117 Berlin
+49 30 246 255 - 0
www.bvmed.de
info@bvmed.de