Bundesverband Medizintechnologie e.V.

Position paper

AI Omnibus and MDR Revision

Strengthening a Sector-First Regulatory Framework for AI Medical Devices

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BVMed supports reinforcing the primacy of the Medical Devices Regulation (MDR) as the applicable sectoral legislation for AI medical devices under a sector-first approach within the AI Act framework, ensuring legal clarity and avoiding duplicative horizontal obligations.

In this context, BVMed welcomes that all three European institutions have already taken steps to advance this approach: the Commission through its proposed revision of the MDR, the European Parliament through sector-first amendments under the AI Omnibus, and Member States through calls for clarification of the interplay between the AI Act and sectoral legislation in the context of industrial AI.

BVMed calls for the swift implementation of these steps to provide legal certainty for industry stakeholders and to ensure that only those AI-related requirements not already covered by the MDR are integrated into its framework to close any remaining gaps vis-à-vis the AI Act.

BVMed – the German Medical Technology Association – supports the EU's digital agenda and the European Commission's objective to foster innovation that benefits patients and healthcare systems. At the same time, Europe's regulatory framework must strengthen — rather than hinder — competitiveness.

Medical technologies are already subject to a comprehensive and mature framework under the Medical Devices Regulation (MDR). The MDR establishes stringent requirements for safety, quality and performance, supported by structured conformity assessment procedures, notified body oversight, harmonised standards, market surveillance and robust post-market obligations.

Additional requirements introduced through horizontal EU legislation must therefore be coherently aligned with, and legally integrated into, the existing MDR framework. Avoiding duplication, legal fragmentation and conflicting obligations is essential.

Under the Artificial Intelligence Act (AI Act) as currently in force, a large proportion of AI medical devices will be classified as high-risk AI systems pursuant to Article 6(1) and will therefore be required to comply with the AI Act as of 2 August 2027.

However, the system required to implement these obligations is not yet operational. At national level, key elements remain pending, including the designation of competent and notifying authorities and the availability of notified bodies authorised under the AI Act. At Union level, harmonised standards enabling manufacturers to demonstrate compliance

are still under development. As a result, manufacturers of AI medical devices cannot meaningfully initiate conformity assessment procedures or plan certification pathways with legal certainty.

With less than two years remaining until application, this situation creates significant regulatory uncertainty. Experience from the MDR transition has shown that complex regulatory systems require sufficient preparation time and full institutional readiness to function effectively.

Proposed legislative adjustments do not yet provide clarity. The AI Omnibus package foresees limited timeline extensions but remains subject to the ordinary legislative procedure, and its final scope and timing remain uncertain. From an industry perspective, any extension must be sufficient and realistic — requiring at least a 24-month adjustment period — to reflect implementation realities.

The amendment to the MDR proposed by the European Commission in December 2025 offers a more coherent structural solution. By moving the MDR from Annex I, Section A to Section B of the AI Act, the Commission clarifies its role as the applicable sectoral framework for AI medical devices. In addition, the amendment enables the integration of relevant AI requirements into Annex I of the MDR through delegated or implementing acts. This approach provides a clear pathway to prevent duplication and ensure legal consistency.

A clear hierarchy between horizontal and sectoral legislation is indispensable to safeguard legal predictability, maintain market access and protect Europe's innovation capacity.

Encouragingly, recent amendments emerging from the European Parliament (LIBE/IMCO committee) reflect growing support for clarifying the precedence of established sectoral legislation and ensuring that this approach is consistently mirrored within the AI Act framework.

Similarly, recent joint statements by EU Member States, including the "Friends of Industry" initiative, underline the need for clarification of the interplay between the AI Act and existing sectoral legislation in the field of industrial AI. These calls reinforce the importance of ensuring coherence between horizontal and sector-specific regulatory frameworks.

Otherwise, there is a real risk that 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.

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