Position Paper
of the German Medical Association

Regarding the proposal of the European Commission COM (2025) 1023 from the 16.12.2025 on the amendment of the Medical Devices Regulation (EU) 2017/745 and the In Vitro Diagnostics Regulation (EU) 2017/746

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1. Preliminary remark

On the 16.12.2026, the European Commission published a long-awaited proposal to amend the Medical Devices Regulation (EU) 2017/745 (hereinafter: MDR) and the In Vitro Diagnostics Regulation (EU) 2017/746 (hereinafter: IVDR). The goal of this proposal is, in particular, to reduce the burden, costs, and duration of conformity assessment procedures while maintaining the standard of patient safety. This is intended to promote innovation in medical devices in the EU while counteracting the discontinuation of medical devices due to economic reasons.

In a letter addressed to the European Commission in 2022, the German Medical Association called for the amendment of the MDR. The German Medical Association supports the aims of the proposed regulation COM (2025) 1023 (hereinafter: the Proposal) and generally welcomes the proposed measures, subject to the following observations.

The comments of the German Medical Association apply mutatis mutandis for the proposed amendment of the IVDR.

The German Medical Association reserves the right to issue further position papers on the proposal or aspects thereof.

2. Position of the German Medical Association

The German Medical Association wishes to comment on the individual elements of the Proposal as follows:

2.1. Requirements for medical devices, which represent or contain high-risk AI systems (Article 4 of the Proposal on Annex I of the Regulation (EU) 2024/1689)

The amendments proposed by the Commission effect the interplay between the MDR and the Regulation (EU) 2024/1689 on Artificial Intelligence (hereinafter: AI Act) and would lead to medical devices, which are or include high-risk AI systems as safety components, no longer being subject to the majority of the provisions of the AI Act. This would also apply to the provisions in Chapter III Section 2, which lays out specific requirements for high-risk AI systems, as well as Article 26, which stipulates the obligations for deployers of these systems.

According to the Commission, AI systems in medical devices should instead be regulated through sector specific provisions. To this end, Article 5 (8) of the Proposal empowers the Commission to amend the relevant general safety and performance requirements for medical devices through delegated acts, or requirements regarding emerging risks or technologies.

The German Medical Association recognises the aim of this approach, but doubts whether the proposed method is suitable for achieving the same level of protection for patients, for the following reasons:

The AI Act stipulates clear obligations for the deployers of AI systems in Article 26. These obligations include, among others, the assignment of human oversight, control over the input data, and the monitoring and notification of incidents. The term “deployer” is central to the AI Act (defined in Article 3 paragraph 4).

The concept of the deployer is absent from the MDR, however, as are the pursuant obligations imposed upon the deployer in the interest of patient safety and the safety of those operating high-risk AI systems. The absence of obligations for the deployer leaves the responsibilities undefined, creating a gap in their protection.

Of particular importance is the need for human supervision. According to Article 14 AI Act, it is a requirement for high-risk AI systems, and according to Article 26 (2) an obligation of the deployer. High-risk AI systems must be designed and developed in such a way that they can be effectively overseen by natural persons who can decide not to use, to disregard, to override or reverse its output, and safely halt the high-risk AI system.

As physicians carry the responsibility for the entire diagnostic and therapeutic decision-making process, they must be in a position to oversee the entire process of diagnosis, therapy, prognosis, and prediction, which also includes the recommendations of machine learning systems. This task cannot be delegated, especially not to AI. Human oversight, therefore, must always be ensured.

Such significant elements cannot be regulated solely through delegated acts, but require regulation in secondary EU law, meaning in the regulation itself. In case the requirements for high-risk AI systems are removed from Chapter III Section 2 of the AI Act, they must be fully integrated in the MDR.

To ensure that future delegated acts based on Article 5 (8) of the MDR, provide the same level of patient safety provided for in the AI Act, human oversight and deployer obligations must be explicitly referenced in Article 5 (8).

The Commission's proposed wording, that the obligations must be "taken into account," should be removed, as its current wording allows for a weakening of requirements.

If the European Parliament and the EU Council should maintain the proposed amendments of Annex I of the AI Act, this amendment must not take effect before the planned specific legislative acts on the requirements for medical devices which incorporate AI systems and on the deployment of AI systems have been adopted and become effective. Otherwise, during the transition period in which the requirements of the AI Act no longer apply to medical devices and the new requirements have not yet become effective, there is a threat of legal uncertainty and reduced patient safety.

Article 4 of the Proposed Regulation COM (2025)1023 on the Amendment of Annex I of the Regulation on Artificial Intelligence (Regulation (EU) 2024/1689)	
Proposal of the Commission	Proposed amendment of the GMA
Annex I to Regulation (EU) 2024/1689 is amended as follows: *(1) in Section A, points 11 and 12 are deleted;* *(2) in Section B, the following points are added:* *'21. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No*	Deletion of the amendment, or: Transposition of the requirements for high-risk AI systems set out in Chapter III Section 2 and in Article 26 of the AI Act into the MDR

178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1); *22. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).'*	
In the event that the aforementioned amendments are not adopted, Article 1 (5) of the proposed regulation COM(2025)1023, concerning the inclusion of Article 5 (7) and (8) of the Medical Devices Regulation, should be amended as follows:	
Proposal of the Commission	Proposed amendment of the GMA
7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. *8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.*	*7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies.* *8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall ~~take into account~~* ***include*** *the requirements set out in Chapter III, Section 2, of that Regulation~~.~~* ***, particularly in regard to human oversight as well as the obligations of the deployer of high-risk AI systems, so that the same level of patient safety is ensured.***

2.2. Liability of manufacturers and authorised representatives for damages caused by defective medical devices (Articles 10 and 11 MDR)

Article 10 of the MDR regulates the general obligations of manufacturers of medical devices. Paragraph 16 stipulates that manufacturers must have measures in place to provide

sufficient financial coverage in the event of liability claims caused by defective products. These measures must be proportionate to the risk class, type of device and the size of the enterprise. This applies without prejudice to more protective liability rules under national law.

Patient protection can, in principle, be achieved in two ways: through ex-ante preventive measures, such as strict conformity assessment regulations, and through ex-post measures, such as providing effective protection for victims in the form of enforceable liability claims in the event of damages. To the extent that ex-ante protection mechanisms are being dismantled, as seems to be the intention of the Commission, ex-post protection mechanisms are becoming more important. Therefore, any simplification and acceleration of the conformity assessment should be paired with stronger rules on liability, in order to prevent the disadvantage of patients.

This could take the form of an obligation for manufacturers of medical devices to procure liability insurance. While the Product Liability Directive (EU) 2024/2853 provides EU wide criteria for the liability of manufacturers, there is no guarantee that claims can be enforced in the event of the manufacturer's insolvency.

Removing Article 10 (6) would have the effect that the prospects for success in claims for damages would largely depend on the Member States where the patient resides. In the PIP breast implant scandal, a decisive incident leading to the proposal of the Medical Devices Regulation, individuals in France who suffered damages were compensated due to national legislation requiring liability insurance. This insurance did not cover individuals outside of France, however. The introduction of Article 10 (16) was a direct consequence of the PIP scandal. It is necessary to retain this Article and potentially expand it.

Article 1 (9) of the Proposed Regulation COM (2025) 1023 on the Amendment of Article 10 MDR	
Proposal of the Commission	Proposed amendment of the GMA
h) paragraph 16 is deleted	~~*h) paragraph 16 is deleted*~~

Article 11 (5) regulates the joint liability of a manufacturer not established in the EU and their authorised representative in the EU in the event of claims for damages arising from a defective device. This is crucial for patients if the enforceability of a liability claim against a manufacturer in a third state is uncertain. Its removal significantly worsens the situation for patients who have suffered damages.

Moreover, the removal of Article 11 (5) would disadvantage European manufacturers of medical devices compared to competitors from third states, as they would be able to evade liability more easily. This can hardly be in the interest of the EU legislator.

Article 1 (11) of the Proposed Regulation COM (2025) 1023 on the Amendment of Article 11 MDR	
Proposal of the Commission	Proposed amendment of the GMA

In Article 11, paragraphs 4 and 5 are deleted	~~*In Article 11, paragraphs 4 and 5 are deleted*~~

2.3. Increasing the reprocessing rate of medical devices / Obligation of justification for single-use devices (Article 17 MDR)

The aim of increasing the reprocessing rate of medical devices is fully supported. This cannot be achieved without binding provisions for manufacturers, as manufacturers often have an economic interest in devising and marketing medical devices as "single-use" products. An obligation to justify the classification of a product as single-use is, in principle, a suitable way of encouraging manufacturers to design and label reusable products accordingly.

2.4. Obligation to report actively exploited vulnerabilities and severe incidents (new Article 87a MDR)

The addition of Article 87a closes a cyber-security gap by placing manufacturers of medical devices on equal footing with manufacturers of other products regarding their obligation to report actively exploited vulnerabilities and severe incidents. This amendment is fully supported.