“Oliver Schenk’s draft report strengthens patient safety and clinical evidence – while further refinements are needed in some areas.”

Statement on Rapporteur Oliver Schenk’s Draft Report on the targeted Revision of the MDR and IVDR
14 July 2026

The German Social Insurance (DSV) welcomes the fact that Rapporteur Oliver Schenk’s draft report, presented on 14 July, strengthens the European Commission’s proposal for a targeted revision of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) in several key areas. The draft report successfully combines the objective of making regulatory procedures more efficient and predictable with a clear commitment to patient safety and robust clinical evidence. In doing so, it preserves and, in some respects, further reinforces essential safeguards contained in the current MDR and IVDR. As the European Parliament begins its deliberations, the draft report provides a solid basis that should be maintained while being further refined in targeted areas.

From the DSV’s perspective, the following amendments are particularly welcome:

_ **Maintaining product liability for manufacturers and authorised representatives:** We welcome the retention of the obligation for manufacturers to ensure adequate financial coverage for potential liability risks, as well as the proposal to require all liable economic operators to maintain adequate financial coverage (Articles 10 and 11 MDR). This preserves a key element of European patient protection. In our view, this approach should be complemented by a mandatory EU-wide liability insurance scheme with risk-based minimum coverage. This would not only strengthen patient protection but also prevent distortions of competition resulting from differing national liability regimes.

_ **Safeguarding product-specific clinical evidence for high-risk devices:** We positively assess the clarification limiting the expanded equivalence provisions in Article 61 MDR, particularly for implantable high-risk devices. This ensures that the safety and performance of such devices continue to be based on robust product-

specific clinical evidence and that the clinical data underpinning regulatory assessments do not become excessively outdated.

_ **Strengthening scientific expertise in regulatory decision-making:** We support the stronger involvement of the Expert Panels, particularly in the context of Articles 54, 106 and 51 et seq. MDR. This will contribute to more consistent and scientifically robust assessments of innovative medical devices.

_ **Prioritised procedures only under strict evidence requirements:** We welcome the amendments to Article 52a MDR, which limit the initial certification of Breakthrough and Orphan Devices to five years, introduce mandatory post-market clinical follow-up (PMCF) measures, and make access to prioritised procedures subject to stricter conditions. These changes strike an appropriate balance between fostering innovation and ensuring patient safety.

_ **Subjecting regulatory sandboxes to clear conditions:** We welcome the clarification in Articles 59b and 59c MDR that participation in regulatory sandboxes does not imply any relaxation of regulatory requirements. This ensures that innovative products must continue to comply fully with all applicable safety and quality standards. To preserve the exceptional nature of this instrument, participation should furthermore be limited to products addressing a demonstrated unmet medical need or providing significant clinical added value, and only where the necessary evidence cannot reasonably be generated through regular regulatory pathways.

At the same time, the DSV considers that several proposals require further refinement:

_ **Maintaining clinical evidence as the cornerstone of conformity assessment:** We oppose the proposed increased reliance on non-clinical data in clinical evaluations under Articles 2 and 61 MDR. Particularly for high-risk devices, clinical evidence must remain the basis of conformity assessment in order to maintain the high level of patient protection established by the MDR.

_ **Preserving transparency requirements for in-house devices:** We oppose the proposed reduction of transparency requirements under Article 5 MDR. Transparency and traceability vis-à-vis patients, competent authorities and other stakeholders must not be weakened, as they are essential for maintaining trust and ensuring effective market surveillance.

_ **Carefully assessing the introduction of a new category of "Niche Devices":** The proposed introduction of a new category of "Niche Devices" under Article 52a

MDR raises concerns regarding its distinction from the existing concept of Orphan Devices and its actual regulatory added value.

_ **Clarifying the classification of software as a medical device:** The proposed amendments to Rule 11 of Annex VIII remain, in our view, insufficiently precise. Whenever software is used to support diagnostic or therapeutic decision-making, a notified body should be involved in the conformity assessment procedure in order to ensure product safety. Furthermore, dedicated classification rules should be established for AI-based medical devices, ensuring that such products are classified at least as Class IIb. Self-learning AI systems should be classified as Class III.

As the legislative process moves forward, the European Parliament should preserve the improvements achieved so far while further refining the draft report in targeted areas. From the DSV's perspective, this applies in particular to the provisions on in-house devices (Article 5 MDR), where an appropriate validity period for the declaration of conformity should be maintained. Furthermore, Articles 61 and 62 MDR should clarify that clinical evaluations based on non-clinical data remain the exception and that clinical investigations must continue to meet the MDR's high standards for clinical evidence. Finally, the classification rules for reusable surgical instruments (Annex VIII, Rule 6 MDR) should be consistently aligned with the actual risk posed by the device, ensuring that instruments used in cardiac and neurosurgery are classified according to their respective risk class.

The DSV will continue to engage constructively in the parliamentary process and remains committed to a balanced revision of the MDR and IVDR that combines regulatory simplification with a high level of patient safety, robust clinical evidence and security of supply.

The DSV's position paper on the European Commission's proposal can be found here.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance with 75 million insured persons, pension insurance with 57 million insured persons and accident insurance with more than 70 million insured persons in 5.2 million member companies offer effective protection against the consequences of major risks of life.