German Social Insurance
European Representation
50 Rue d'Arlon
1000 Brussels
Belgium

Phone: +32 2 282 05-50
info@dsv-europa.de
www.dsv-europa.de
Transparency Register ID:
917393784-81

Deutsche Sozialversicherung
Europavertretung | DSV

Opinion from German Social Insurance issued 19 March 2026

Proposal for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

Table of Contents

I. Preliminary remark **3**

II. Opinion **8**

1 _ Article 1 amending Regulation (EU) 2017/745 (“MDR”) **8**

2 _ Article 4 amending Regulation (EU) 2024/1689 (“AI Act”) **23**

3 _ Annex **24**

I. Preliminary remark

With the Regulation proposal presented on 16 December 2025 to simplify the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR), the European Commission aims to simplify certification procedures, reducing administrative burdens and accelerating market access for medical devices. The regulatory framework is to be streamlined and future-proof to improve predictability and efficiency of procedures, reduce costs, remove barriers to innovation and ensure the availability of medical devices.

Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) constitute the central European legal framework for ensuring the quality and safety of medical devices and diagnostics. They are therefore key pillars of patient protection and of a high-quality, evidence-based healthcare system in the European Union (EU).

With the Regulation proposal, the European Commission intends to amend the MDR and IVDR to a significant extent. The proposed adjustments go far beyond mere “technical fixing”: more than three quarters of the articles of the MDR are amended in wording or substance. This constitutes a profound reform of the existing regulatory framework with potentially far-reaching implications for patient safety, quality of care, clinical evidence requirements and market surveillance. The European Commission bases its proposal largely on evaluations and feedback from stakeholders regarding the practical implementation of the MDR and IVDR. At the same time, publicly available, comprehensible, robust and systematically collected data are still lacking, for example on market withdrawals, supply shortages or national derogations.

The German Social Insurance (DSV) considers that a particularly careful assessment is required as to whether and to what extent regulatory simplifications are justified and what unintended consequences they may entail. The statutory health insurance funds are responsible for providing safe, effective and high-quality care to around 75 million insured persons in Germany. Uniform European requirements for clinical evidence, market surveillance and traceability are essential to minimise treatment risks, ensure quality of care and strengthen the trust of patients and medical professionals in medical devices and diagnostics. At the same time, reliable and needs-based provision of medical devices and in vitro diagnostic medical devices is essential for statutory health insurance. Shortages, market withdrawals or non-transparent special arrangements have a direct impact on the care of insured persons and on service providers.

Amendments to the MDR and IVDR are appropriate where they specifically reduce bureaucracy, make procedures more efficient and improve practical implementation

without jeopardising the core objectives of the Regulations – a high level of protection for patients, evidence-based approval decisions and effective market surveillance.

Against this background, the DSV considers that the following points should be taken into account in the discussions on the revision of the MDR and IVDR:

Ensure clinical evidence and patient safety

The DSV rejects provisions that would lead to a lowering of requirements for clinical evidence and patient safety. A clinical evaluation without sufficient clinical data constitutes a contradiction and endangers patient safety and quality of care.

At the same time, the DSV expressly welcomes the planned approaches for the early involvement of expert panels in the clinical development and evaluation strategy of medical devices. Structured scientific advice at early stages can help to define evidence requirements more clearly, align studies more effectively and avoid undesirable developments in the conformity assessment procedure.

The DSV therefore calls for:

_ **clinical evaluation of medical devices to be based, in principle, on robust clinical data. Non-clinical data may complement clinical data and may only replace them in very limited exceptional cases (Art. 61 MDR),**

_ **clinical studies involving medical devices already placed on the market, when used outside their intended purpose, should remain subject to the MDR authorisation, transparency and supervisory requirements (Art. 62 MDR),**

_ **the scrutiny procedure pursuant to Art. 54 MDR and Art. 50 IVDR not to be restricted but to be extended to further care-relevant high-risk medical devices, as these assessments constitute a central prerequisite for initiating EU HTA procedures and thus enable reimbursement decisions by health insurance funds,**

_ **a waiver of own clinical investigations based on claimed equivalence to be permitted only if the clinical evaluation of the equivalent product is based on a clinical investigation demonstrably conducted in compliance with the MDR (Art. 61(5) MDR),**

_ **regulatory sandboxes to be used exclusively with clear substantive safeguards and solely for the purpose of structured evidence generation (Art. 59b and 59c MDR / Art. 54b and 54c IVDR).**

Limit special regimes for orphan, breakthrough and WET devices

The DSV expressly welcomes that product categories such as orphan devices, breakthrough devices and well-established technologies (WET) are explicitly regulated in the legal text for the first time. This increases transparency, legal certainty and the clarity of procedures. It is also acknowledged that targeted procedural facilitations are envisaged for these product categories to promote innovation and enable care for small patient groups.

However, these special regimes must not lead to a de facto lowering of patient safety. The fundamental requirements for clinical evidence and market surveillance must fully apply to these product categories as well, or exemptions must be limited to products for which application risks can largely be excluded.

The DSV therefore calls for:

_ **certification conditions and structured programmes for generating the necessary clinical data to close evidence gaps alongside market placement,**

_ **regular reassessment of the benefit-risk profile, the evidence base and the relevance for care,**

_ **maximum review periods of five years – both for (legacy) orphan and breakthrough devices and for other exceptional arrangements such as in-house products (e.g. Art. 5 and 120 MDR / Art. 5 and 110 IVDR).**

Strengthen binding transparency in market surveillance and supply shortages

The DSV expressly welcomes the strengthening of transparency regarding supply shortages and the expansion of reporting and early warning systems. Early information on imminent or existing shortages is a key prerequisite for safe, coordinated and reliable supply of medical devices.

The DSV therefore calls for:

_ **mandatory publication and regular updating of reported data on supply shortages, in particular based on notifications pursuant to Art. 10a MDR / IVDR,**

_ **the continued and strengthened publication of national derogations pursuant to Art. 59 MDR / Art. 54 IVDR,**

_ **strengthened information flows in market surveillance: preventive and corrective measures by manufacturers (Art. 83 MDR / Art. 78 IVDR) must be communicated automatically, systematically and comprehensively to the competent authorities.**

Ensure liability and patient rights consistently

Previous medical device scandals – in particular the PIP case – have shown that clear liability rules and sufficient financial coverage by manufacturers are indispensable for effective patient protection. The proposed deletion of these provisions constitutes a clear step backwards.

The DSV therefore calls for:

_ **maintaining and strengthening manufacturer liability,**

_ **mandatory financial coverage of potential liability claims,**

_ **maintaining joint and several liability of authorised representatives,**

_ **introducing an EU-wide mandatory liability insurance for manufacturers.**

Use digitalisation as an efficiency lever

The DSV expressly welcomes the digitalisation of documentation and evaluation processes as an opportunity for more efficient procedures, increased transparency and reduced administrative burden.

The DSV considers:

_ **digital procedures must be interoperable, versioned and machine- and human-readable,**

_ **digitalisation must not lead to reductions in the depth of assessment or regulatory oversight.**

II. Opinion

This statement focuses primarily on the proposed amendments to the Medical Devices Regulation (MDR). Where the Regulation proposal provides for parallel or corresponding amendments to the In Vitro Diagnostic Medical Devices Regulation (IVDR), the following assessments and comments apply mutatis mutandis to the respective amendments to the IVDR.

1 _ Article 1 amending Regulation (EU) 2017/745 ("MDR")

Number 5 – Amendment of Article 5 MDR

Proposed amendment
Article 1(5) of the proposed amending Regulation aims to amend Article 5 of Regulation (EU) 2017/745 ("MDR"). Article 5 currently governs the placing on the market and putting into service of medical devices. It is proposed to add a new subparagraph concerning the conditions for in-house manufacture of medical devices by health institutions.

In the future, health institutions shall be allowed to continue to manufacture and use an in-house device even if an equivalent CE-marked product is available on the market. If the health institution becomes aware that the specific needs of the respective target patient group could in principle also be met by a product available on the market, the in-house device shall nevertheless be allowed to continue to be used for a period of up to ten years.

Assessment
The DSV considers the envisaged extension of the permissible continued use of in-house manufactured devices to up to ten years to be critical, as it clearly goes beyond the existing system. The European Commission intends to provide health institutions with greater scope for action and use for their in-house developments and thereby create incentives for innovative developments. However, a period of ten years does not appear appropriate. Under the previous legal framework, the permissibility of in-house manufacture ended as soon as a CE-marked product with the same intended purpose became available; in addition, certificates under the previous directives generally had a maximum validity of five years.

Any continued use of in-house manufactured devices beyond this period is critical from a patient protection perspective. Where an equivalent CE-certified medical device is available, its use should in principle take precedence, as such products are

subject to harmonised requirements regarding quality, safety and performance as well as external conformity assessment. An extension of the continued use of in-house manufactured devices to up to ten years entails significant risks for patient protection and undermines the objective of the MDR to ensure a high and uniform level of safety within the European internal market.

The DSV therefore calls for limiting the period of continued use of in-house manufactured devices to five years following the placing on the market of an equivalent CE-certified medical device.

Number 9 – Amendment of Art. 10 MDR

Proposed amendment
Article 1(9) of the proposed Regulation aims to amend Article 10 (“General obligations of manufacturers”) of the MDR. It is envisaged to delete the obligation to carry out a clinical evaluation, including post-market clinical follow-up, as well as obligations relating to the UDI system and registration requirements.

In addition, the explicit obligation to establish a post-market surveillance system, including obligations to report incidents and to carry out corrective safety actions, is to be removed. The requirements for the quality management system of manufacturers are also to be redefined.

Furthermore, the proposal provides for a new regulation of documentation requirements in cases of outsourced development or manufacture, as well as the deletion of the explicit provision on manufacturer liability and on the obligation to provide financial coverage for potential liability claims.

Assessment
The DSV considers the envisaged amendments to Article 10 MDR to be highly critical. With the deletion of Article 10(14) MDR, information obligations vis-à-vis patients and payers – and thus health insurance funds – would cease to apply, thereby significantly impairing transparency and the enforcement of rights.

Article 10(16) MDR, as previously in force, for the first time obliged manufacturers EU-wide to take measures, appropriate to the level of risk and takeing into account their size, to ensure sufficient financial coverage of their liability risks. This provision provided injured patients with a first real chance of compensation.

A meaningful amendment of the MDR would therefore be to further develop this provision into a mandatory liability insurance for medical device manufacturers, which had originally been called for by both the DSV and the European Parliament during the MDR legislative process. Instead, the provision is now to be deleted without justification.

This is contrary to the key lessons learned from the breast implant scandal (PIP). Only in France does a mandatory liability insurance exist, with the consequence that only injured patients in France were compensated, while affected persons and payers in other Member States received no compensation.

The DSV therefore considers the deletion – contrary to the necessity of an EU-wide liability insurance obligation – to be a clear step backwards for patient rights and for the protection of the solidarity-based system.

Number 10 – Amendment of Article 10a MDR

Proposed amendment
With Number 10, Article 10a MDR is to be further developed and the existing early warning system for shortages of medical devices expanded.

Manufacturers shall be obliged to inform the competent authorities at least six months before a planned interruption or discontinuation of supply, or otherwise without delay after becoming aware of it; the reasons for the interruption or discontinuation shall also be provided.

In future, not only manufacturers but also users, health institutions and healthcare professionals shall be able to report impending or existing shortages as well as supply problems. To support these reports, the Commission shall establish an electronic reporting system interoperable with EUDAMED.

Furthermore, the European Medicines Agency (EMA) shall be tasked with developing, together with the Steering Group on Shortages of Medical Devices (MDSSG), a methodology for identifying particularly critical medical devices.

Assessment
The expansion and specification of reporting obligations in Article 10a is expressly welcomed by the DSV. The possibility that, in future, not only manufacturers but also users and health institutions can report shortages represents an important step

towards a more comprehensive and realistic early warning system. The DSV considers that these provisions for the first time enable the Commission and the EMA to systematically collect information on market withdrawals, production interruptions and other supply-relevant events.

To fully exploit the benefits of this early warning system, the DSV considers mandatory publication and regular updating of the reported data to be necessary.

Furthermore, it should be noted that the proposal does not yet consider that manufacturers should generally be obliged to inform downstream distributors and other economic operators at an early stage about the discontinuation of supply – irrespective of whether a concrete risk of shortage already exists.

Number 11 – Amendment of Article 11 MDR

Proposed amendment
With Number 11 of the Regulation proposal, paragraphs 4 and 5 of Article 11 MDR are to be deleted. This would remove, firstly, the explicit clarification that key obligations of the manufacturer under Article 10 cannot be delegated to the authorised representative.

Secondly, the currently provided joint and several liability of the authorised representative for defective products shall be abolished in cases where the manufacturer is established outside the EU and fails to fulfil its obligations. Overall, this would significantly reduce the legal responsibility of the authorised representative.

Assessment
The DSV considers the proposed amendments to Article 11 MDR to be highly critical. The removal of joint and several liability of authorised representatives eliminates a key element of the MDR's system of responsibility and liability. This would significantly weaken both the enforceability of patient rights and the protection of the solidarity-based system, particularly in cases involving manufacturers established outside the European Union.

The abolition of this liability provision is not comprehensible for the DSV. Product liability was a key lesson learned from previous medical device scandals such as the PIP case, in which insufficient liability and responsibility structures led to considerable disadvantages for patients and payers.

The envisaged reduction of responsibility for authorised representatives therefore constitutes a step backwards for patient protection and legal enforcement in European medical device law.

Number 15 – Amendment of Article 17 MDR

Proposed amendment
With the revision of Article 17 MDR, the provisions on single-use devices and their reprocessing are to be fundamentally revised. In the future, manufacturers shall be required to provide justification as to why a medical device is intended exclusively for single use. This shall only be permissible where they cannot ensure that reuse after appropriate reprocessing would continue to meet the safety and performance requirements.

For devices not intended as single-use products, specific information on appropriate reprocessing procedures shall be mandatorily included in the instructions for use.

Furthermore, it shall be clarified that, in the case of reprocessing of single-use devices, the reprocessor shall be considered the manufacturer and shall assume the corresponding manufacturer obligations.

Assessment
The DSV generally welcomes the revision of Article 17 MDR. It contributes to clearer allocation of responsibilities and greater transparency in the classification of medical devices as single-use or reusable products.

It is particularly positive that manufacturers must justify the designation of a product as single-use and that, in cases of reprocessing, the responsibility clearly lies with the reprocessor. At the same time, the provision creates incentives for the development of reusable medical devices by making blanket classification as single-use more difficult.

However, certain product groups must, by their nature, remain single-use devices (e.g. sterile materials for wound care such as plasters or certain dressings, or single-use needles and syringes). Therefore, a clarifying limitation should be introduced stating that the obligation to provide justification does not apply to such products. This would ensure that unnecessary administrative burdens are not imposed on manufacturers.

Number 24 – Amendment of Article 32 MDR

Proposed amendment
With the amendment of Article 32 MDR, the structure of the summary of safety and clinical performance (SSCP) is to be adapted. A requirement for a patient-friendly presentation is no longer explicitly provided.

Furthermore, the procedure for making the summary available is to be modified: manufacturers shall ensure that the SSCP is publicly accessible via EUDAMED, while the draft remains part of the conformity assessment documentation.

Assessment
The DSV considers that the proposed amendments to Article 32 MDR are critical. The removal of an explicitly patient-friendly summary of safety and clinical performance makes it more difficult for patients to make informed decisions regarding planned therapeutic interventions.

The DSV therefore calls for a patient-friendly presentation for all devices in the relevant risk classes, particularly for those used directly by patients or associated with immediate risks.

Number 43 – Amendment of Article 52 MDR

Proposed amendment
With the amendment of Article 52(3) MDR, a simplified conformity assessment procedure shall be introduced for Class III medical devices that are considered well-established technology devices (WET).

By way of derogation from the previous principle, according to which Class III devices are subject to a full conformity assessment in accordance with Annex IX or alternatively Annex X in conjunction with Annex XI, WET devices shall in future be subject exclusively to the procedure under Annex IX Chapters I and III. In this context, the assessment of the technical documentation shall be limited to one representative device per generic device group. Previously, a comprehensive individual assessment was required for Class III devices.

Assessment
The DSV considers that the proposed special provision for Class III medical devices classified as WET raises fundamental issues of delineation. It is unclear which products of the highest risk class can in fact be classified as WET; conceptually, this largely appears to be mutually exclusive.

The European Commission should clarify in advance whether, in practice, there are Class III devices that can be classified as WET. If no corresponding product categories are included in the WET list yet to be published, the provision would be effectively without subject matter and should be deleted for reasons of legal clarity.

Number 44 – Amendment of Articles 52a and 52b MDR

Proposed amendment
With the introduction of a new Article 52a, breakthrough devices (BTD) and orphan devices (OD) shall for the first time be explicitly regulated in the legal text of the MDR. The provision shall define the criteria for these product categories, establish the procedure for determining status and provide that the determinations of the competent expert panels pursuant to Article 106 shall be published.

For orphan devices and breakthrough devices, the existing conformity assessment procedures under Article 52 MDR shall in principle apply, supplemented by specific procedural facilitations. Upon application by the manufacturer or the notified body, an expert panel shall assess whether the conditions for the respective status are fulfilled. Where the assessment is positive, the manufacturer shall additionally be able to seek scientific advice on the clinical development strategy as well as on appropriate pre-clinical or clinical data.

For confirmed orphan devices and breakthrough devices, notified bodies shall be required to prioritise the conformity assessment procedure and, where appropriate, to apply a rolling review procedure to shorten the duration of the assessment. Furthermore, Article 52a(7) shall provide that a conformity certificate may also be granted based on limited clinical data, provided that one of the following criteria is fulfilled:

> a) the benefit of immediate availability of the product on the market outweighs the risks arising from the absence of further clinical data, or
> b) the benefit-risk ratio is positive, and the manufacturer undertakes to collect additional data within the framework of post-market clinical follow-up (PMCF).

The validity of such certificates may be limited in time and made subject to conditions.

In addition, the new Article 52b shall explicitly allow the digital creation and provision of technical documentation as well as conformity assessment documentation. Manufacturers shall in future be able to maintain these documents in a digital, including machine-readable, format, if conversion into a human-readable format and reliable version control are ensured. The specific format shall be agreed with the notified body. To ensure interoperability and standardisation, the Commission may establish minimum requirements for digital formats through common specifications.

Assessment
The clear and transparent definition of orphan devices and breakthrough devices provided for in Article 52a is, in principle, welcomed by the DSV. The clear regulation of product categories, the establishment of a transparent procedure for determining status and the envisaged publication of the determinations of expert panels pursuant to Article 106 increase transparency and legal certainty and contribute to a uniform application within the EU. The prioritisation of conformity assessment and the possibility of a rolling review procedure may also be appropriate from a procedural perspective.

However, the possibility of certification provided for in Article 52a(7)(a) based on the criterion of the “benefit of immediate availability of the product on the market” is to be assessed critically. The DSV considers it unclear which benefit is intended here, if it is not the application-related, patient-specific benefit within the framework of the benefit-risk ratio. The patient-related benefit-risk ratio must always be the primary consideration.

The DSV considers that the wording of point (a) excessively lowers the requirements for the clinical evaluation of orphan devices and breakthrough devices, is substantively unnecessary and should be rejected. It entails the risk that products with insufficiently substantiated clinical evidence are placed on the market solely because of the asserted necessity of rapid market availability. By contrast, the linkage provided for in point (b) to a positive benefit-risk ratio and mandatory PMCF data collection appears appropriate and sufficient.

The provisions in Article 52b concerning the digitalisation of technical documentation, conformity assessment and reports are expressly welcomed by the DSV. They offer considerable potential for increasing efficiency, accelerating procedures and reducing administrative burdens without compromising regulatory requirements regarding quality, traceability and oversight.

Number 45 – Amendment of Article 53 MDR

Proposed amendment
With the amendment of Article 53(5) MDR, it shall be clarified that notified bodies and their personnel must carry out their conformity assessment activities in the public interest.

Assessment
The DSV expressly welcomes the explicit emphasis on the performance of tasks by notified bodies in the public interest. It makes clear that conformity assessment procedures do not constitute purely private economic services but rather fulfil a central protective function for patient safety and quality of care. Against this background, any provision that strengthens the understanding of notified bodies that they are to carry out their activities in the public interest and independently of economic interests is to be welcomed.

Number 46 – Amendment of Article 54 MDR

Proposed amendment
With Article 1(46), Articles 54 and 55 MDR are to be revised and the procedures for the expert review of high-risk medical devices are to be specified.

For implantable Class III medical devices, the mandatory involvement of expert panels within the framework of the Clinical Evaluation Consultation Procedure (CEPC) shall, in principle, remain in place. At the same time, additional exemptions shall be introduced, for example in the case of certificate renewals, certain product modifications without negative impact on the benefit-risk ratio, or where the clinical evaluation is already covered by harmonised standards or common specifications.

The role of notified bodies shall be strengthened and made more transparent: they shall be required to disclose whether the consultation procedure was applied, to submit clinical evaluation reports electronically and to take due account of the opinions of expert panels; deviations shall have to be justified.

Article 55 shall be further developed into a general scrutiny mechanism for conformity assessments, enabling the MDCG and the Commission to involve expert panels or expert laboratories at any time in the event of justified concerns regarding safety or performance – including after certification.

Assessment
The DSV expressly welcomes the strengthened and more transparent role of notified bodies. The mandatory disclosure of whether the consultation procedure has been applied, the electronic submission of clinical evaluation reports and the increased binding nature of the opinions of expert panels can contribute to greater transparency, quality assurance and consistency in the conformity assessment of high-risk medical devices.

The envisaged limitation of the CEPC under Article 54 to implantable Class III medical devices must, however, be assessed critically. Whereas previously certain Class IIb medical devices – particularly those administering or removing medicinal products – were also subject to the scrutiny procedure, the scope is now significantly narrowed.

This restriction is particularly problematic since assessments under Article 54 constitute the central trigger criterion for European Health Technology Assessment (EU HTA). A reduction of the scope of the scrutiny procedure therefore directly leads to a restriction of the HTA scope for medical devices and weakens the systematic assessment of benefit, evidence base and relevance for care.

The DSV considers it necessary to extend the scrutiny procedure to all breakthrough devices of Classes IIb and III – including non-implantable devices. For these products, a structured and transparent assessment of the available evidence is indispensable to create a sound basis for reimbursement decisions.

Number 49 – Amendment of Article 59 MDR

Proposed amendment
With the proposed amendment of Article 59 MDR, the provisions on national derogations are to be specified and expanded. Competent authorities shall continue to be able to authorise the placing on the market, putting into service or the provision of diagnostic or therapeutic services with non-conformity assessed medical devices, provided this is in the interest of public health, patient safety or patient health.

Such decisions shall now be time limited.

Derogations extending beyond use for an individual patient shall be made transparent and published. Member States shall communicate such decisions to the

Commission, the other Member States and the competent expert panels, and shall make the information publicly accessible.

In addition, the European Commission shall be empowered, in exceptional cases, in Union-wide recognised public health emergencies, to extend national derogations to the Union level or to grant such derogations itself.

Assessment
The clarification that national derogations from the regular conformity assessment procedure must be time-limited and transparent is expressly welcomed by the DSV. The mandatory publication of derogations and the Union-wide information of the Commission, Member States and expert panels strengthen transparency and coherence of the European regulatory framework.

The proposal therefore makes an important contribution to avoiding non-transparent national special pathways.

Number 50 – Amendment of Articles 59a, 59b and 59c MDR

Proposed amendment
With the new Articles 59b and 59c, a Union-wide legal framework for regulatory sandboxes in the field of medical devices shall be established for the first time.

Member States shall be able to establish time-limited national or joint sandboxes to deviate from or adapt certain MDR requirements for specific medical devices, regarding classification, clinical evaluation, clinical investigations or conformity assessment procedures. The establishment of a sandbox may be initiated by competent authorities or upon justified request by manufacturers, provided that an unmet medical need or a significant clinical benefit can be expected and existing MDR requirements significantly hinder market access. Each sandbox shall require a sandbox plan including objectives, scope, duration as well as risk and monitoring measures. Supervision shall lie with the competent authorities; manufacturers shall remain responsible for safety and performance.

In addition, Article 59c provides for the establishment of Union-wide regulatory sandboxes by the European Commission. These shall be time-limited and based on a specific plan to assess the appropriateness of existing MDR requirements. However, Union-wide sandboxes shall not allow the placing on the market or putting into service of non-MDR-compliant devices.

Assessment

The DSV considers that the introduction of regulatory sandboxes in the field of medical devices requires a differentiated assessment and is overall critical. The proposed provisions open the possibility of suspending key MDR requirements and thus entail the risk that fundamental protection mechanisms are weakened and that an alternative pathway alongside the regular conformity assessment procedure is established. In addition, the scope of application remains unclear. While the rationale appears to focus on breakthrough and orphan devices, the wording of the Regulation is significantly broader and allows deviations beyond these narrowly defined categories.

Without clearer limitations, there is a risk that regulatory sandboxes are not used as a narrowly defined exception but as a flexible circumvention instrument.

Number 52 – Amendment of Article 61 MDR

Proposed amendment

With Article 1(52), the provisions on clinical investigations of medical devices in Article 61 MDR on clinical evaluation are to be adapted. Manufacturers shall continue to be obliged to plan, carry out and document a clinical evaluation. At the same time, they shall be granted greater flexibility in determining and justifying the required level of clinical evidence. They shall consider whether and to what extent conformity of a device can also be demonstrated based on non-clinical data pursuant to Article 61(10). Furthermore, the possibility of early consultation with expert panels for Class IIb and III devices shall be explicitly provided for. The obligation to conduct clinical investigations for implantable devices and Class III devices shall be specified and supplemented by additional exemptions, for WET.

In addition, the use of existing clinical evaluations in cases of demonstrated equivalence shall be facilitated. Manufacturers shall be allowed, in cases of demonstrated equivalence to a device already placed on the market by another manufacturer, to waive their own clinical investigations without having full access to its technical documentation. The condition shall be that the original clinical evaluation of the equivalent device was conducted in compliance with the MDR and that this can be clearly demonstrated to the notified body.

Furthermore, it shall be clarified that, in justified cases, conformity assessment may also be based on non-clinical data.

Assessment
The earlier involvement of expert panels in the clinical development strategy for manufacturers of Class IIb and III devices is generally welcomed by the DSV, as it can contribute to greater clarity and predictability in the conformity assessment procedure and lead to more meaningful clinical data.

However, it must be assessed critically that Article 61(1) is now intended to explicitly provide that manufacturers, when determining the required level of evidence, should examine whether conformity of a device can also be demonstrated based on non-clinical data. A clinical evaluation that is based essentially or exclusively on non-clinical data constitutes, from the perspective of the DSV, a contradiction and should remain an absolute exception – at most conceivable for devices of lower risk classes or for clearly defined WET.

The planned amendments to Article 61(5) are also to be assessed ambivalently. It is justified that the Commission intends to create simplifications and move away from the previous requirement that manufacturers must have full access to the technical documentation of an equivalent device of another manufacturer to waive their own clinical investigations – a requirement that is hardly feasible in practice.

At the same time, however, this requirement was deliberately introduced to prevent so-called “grandfathering”, i.e. the continued reliance of entire product classes on outdated clinical data of earlier generations. This problem is particularly known from the field of endoprosthetics.

The DSV considers it essential to clarify that a waiver of own clinical investigations is only permissible if the original clinical evaluation of the equivalent device, including its own clinical investigation, was demonstrably conducted in full compliance with the MDR. Without such clarification, there is a risk that the objective of the MDR to ensure a solid and up-to-date clinical evidence base for medical devices will be undermined.

Number 53 – Amendment of Article 62 MDR

Proposed amendment
With the revision of the introductory sentence of Article 62 MDR, it shall be clarified that the detailed requirements for clinical investigations shall only apply to investigational devices that have not yet been placed on the market or put into service in accordance with the MDR.

Clinical studies for the evaluation of already compliant and placed on the market medical devices shall therefore no longer necessarily fall within the scope of the MDR and may be conducted outside its scope.

Assessment
The DSV considers the proposed restriction of the scope of clinical investigations to be ethically and regulatorily highly problematic. It potentially entails significant consequences also for national legal frameworks, as it implies that medical devices already placed on the market may be evaluated in clinical studies without being subject to the binding requirements of the MDR. This is particularly critical in constellations where manufacturers de facto control or finance investigator-initiated trials (IITs) and thereby investigate benefits, safety or new applications of marketable devices outside their intended purpose. In such cases, there is a risk that central protection, transparency and authorisation requirements of the MDR are circumvented.

The DSV considers it essential to clarify the scope of clinical investigations and not to restrict it as far as currently proposed. Clinical studies should also be subject to MDR requirements where they are conducted with devices already placed on the market, where they are carried out outside the intended purpose. A corresponding clarification of the wording is necessary for ethical reasons and for the protection of patients.

Number 65 – Amendment of Article 83 MDR

Proposed amendment
With the amendment of Article 83(4) MDR, the obligation of manufacturers to provide information to competent authorities within the framework of market surveillance shall be weakened.

Manufacturers shall remain obliged to implement identified preventive or corrective measures. However, they shall no longer be required to automatically inform the competent authorities. Instead, authorities shall be given the possibility to request such information from manufacturers on a case-by-case basis.

Assessment
The DSV considers this reduction of information obligations to be critical. It remains unclear whether and to what extent competent authorities will in future receive less

information on relevant incidents and on subsequent preventive or corrective measures taken by manufacturers.

This raises the question of how effective market surveillance can be ensured if authorities are no longer regularly and automatically informed of safety-relevant measures.

Number 95 – Amendment of Article 120 MDR

Proposed amendment
With the addition of new paragraphs 14 and 15 to Article 120 MDR, additional transitional and special provisions shall be introduced, in particular for legacy orphan devices. For medical devices that fall under existing transitional provisions and meet the criteria of an orphan device pursuant to Article 52a, it shall be possible to continue placing them on the market or putting them into service beyond the existing transitional periods, even if they do not yet hold a CE certificate.

Conditions shall include, inter alia, a positive opinion from an expert panel, the absence of significant changes to the device and an acceptable safety profile. These devices shall continue to be subject to certain MDR requirements, regarding market surveillance and post-market clinical follow-up but shall not bear a CE marking and shall be labelled as orphan devices.

Competent authorities shall be able to require additional post-market studies. Review by an expert panel shall only take place every ten years.

In addition, it is envisaged that, in ongoing conformity assessment procedures, manufacturers and notified bodies may continue to apply the existing MDR framework for a limited period until completion or renewal of certification.

Assessment
The proposed provision aims to ensure that legacy orphan devices for very small patient groups can continue to be placed on the market on a permanent basis via a special pathway in the sense of a grandfathering mechanism, without requiring full MDR certification. This may concern highly specialised products, for example in paediatric or interventional cardiology. This is acknowledged.

However, the envisaged review cycle of ten years for confirming orphan device status is problematic. Such a long period effectively facilitates a permanent circumvention of

MDR certification and undermines the objective of regular, evidence-based reassessment of safety and performance, also considering newly introduced therapeutic alternatives.

The DSV therefore considers a significantly shorter time limit to be necessary and calls for a maximum review period of five years.

2 _ Article 4 amending Regulation (EU) 2024/1689 ("AI Act")

Number 1 – Amendment of Annex I AI Act

Proposed amendment
With the amendment of Annex I to Regulation (EU) 2024/1689 (Artificial Intelligence Act), the MDR and IVDR shall be moved within the system of the AI Act from Section A to Section B.

This would mean that AI systems used as safety components in medical devices would no longer automatically be classified as high-risk AI. Instead, a case-by-case assessment would be required.

A system would only qualify as high-risk AI if:

- the medical device is subject to conformity assessment involving a notified body, and
- the AI performs a safety-relevant function or significantly influences clinical decision-making.

Furthermore, the Commission shall be empowered to adopt delegated acts establishing additional requirements for AI in medical devices. Notified bodies shall be required to demonstrate specific AI expertise.

Assessment
Avoiding regulatory overlaps between the AI Act and MDR/IVDR is, in principle, justified. However, the AI Act contains requirements that are not equally reflected in MDR/IVDR, for example regarding fundamental rights, robustness or data quality. If the reclassification leads to certain requirements no longer applying automatically, it is essential that the level of safety is not reduced.

The DSV therefore considers it essential that all requirements relating to product safety, patient safety and the protection of fundamental rights continue to apply. Requirements that may fall away should be integrated into the MDR and IVDR.

3 _ Annex

Number 6g – Amendment of Annex VIII (Rule 11 MDR)

Proposed amendment
With the revision of Annex VIII, Rule 11, the classification of software as a medical device shall be fundamentally restructured.

Software intended to generate an output with clinical benefit shall be classified as Class I, unless the output is used for:

- a critical situation (Class III)
- a serious situation (Class IIb)
- a non-serious situation (Class IIa)

Assessment
The DSV considers the revision of Rule 11 to be critical. On the one hand, it remains unclear which diseases or conditions fall under “non-serious situations” and would therefore be classified as Class I. On the other hand, Class I is effectively established as the default category for software with clinical benefit, while higher classes only apply in explicitly defined risk scenarios. This internal contradiction has not been resolved. If this leads to most clinical decision-support software being classified as Class I, it would have significant consequences for the regulatory level of protection.

Such a development would not be acceptable to the DSV, particularly regarding digital health applications reimbursed by statutory health insurance. Lower testing, safety and evidence requirements would contradict the objectives of the MDR and pose risks to patient safety and quality of care.

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.