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Bundesministerium für Gesundheit
Referat 123
Referat 124
Berlin/Bonn

MDR / IVDR Revision Verbändeposition

Berlin, 10. April 2026

Anrede,

der am 16. Dezember 2025 vorgelegte Kommissionsvorschlag zur Änderung der MDR und IVDR wird von den unterzeichnenden Verbänden grundsätzlich positiv bewertet.

Erste Analysen der Industrie zeigen, dass er **zentrale und dringend notwendige Maßnahmen enthält**, um die Funktionsfähigkeit des europäischen Marktes sicherzustellen sowie Innovationshemmnisse, administrative Lasten und Unsicherheiten im aktuellen System zu reduzieren und damit die Versorgungssicherheit zu stärken.

Eine **zügige Verabschiedung und Implementierung sind zentral**, um bestehende Herausforderungen, Engpässe und Wettbewerbsnachteile auf europäischer Ebene nicht weiter zu verschärfen. Daher haben wir uns mit den beiliegenden Ausarbeitungen zu spezifischen Themen auf die wesentlichen Punkte fokussiert und damit nicht alle positiv und negativen Punkte abschließend aufgenommen und ausformuliert.

Die Verbände empfehlen daher der Bundesregierung die in den Anlagen dargestellten **Vorschläge zur Anpassung und Präzisierung des Kommissionsvorschlags** in ihre Position für die Beratungen im Rat der Europäischen Union einzubeziehen und sich zugleich dafür einsetzt, die positiven Ansätze des Kommissionsvorschlags zur Erreichung des übergeordneten Ziels der Vereinfachung und Effizienzsteigerung im Bereich der MedTech- und IVD-Branche im weiteren Gesetzgebungsverfahren zu bewahren.

Die Verbände stehen für eine konstruktive Zusammenarbeit und Rückfragen zur Verfügung.

Mit freundlichen Grüßen

Im Namen der zeichnenden Verbände

MDR-IVDR Onepager zum Revisionsvorschlag in der Anlage:

- Anlage 01_MDR-IVDR Revision Onepager_Conformity Assessment
- Anlage 02_MDR-IVDR Revision Onepager_Structured_dialogue
- Anlage 03_MDR-IVDR Revision Onepager_Access to NB and Fees
- Anlage 04_MDR-IVDR Revision Onepager_WET
- Anlage 05_MDR-IVDR Revision Onepager_Art. 10a
- Anlage 06_MDR-IVDR Revision Onepager_OEM-PLM
- Anlage 07_MDR-IVDR Revision Onepager_Art. 17
- Anlage 08_MDR-IVDR Revision Onepager_BtX and OD
- Anlage 09_MDR-IVDR Revision Onepager_Rule 6&7
- Anlage 10_MDR-IVDR Revision Onepager_Rule 11
- Anlage 11_MDR-IVDR Revision Onepager_Orphan IVDs
- Anlage 12_MDR-IVDR Revision Onepager_IVDR Active Ingredients
- Anlage 13_MDR-IVDR Revision Onepager_IVDR Routine Blood Draws

MDR - IVDR Revision | Onepager | Conformity Assessment

April 2026

Introduction

The MDR/IVDR proposal through changes to the conformity assessment procedure aims to reduce the bottleneck in the notified body system, to create more efficient assessment pathways while maintaining the high level of patient and user safety.
The focus is on a stronger risk-based and approach, targeted use of resources, and facilitating processes for proven products and technologies.
We welcome the proposed changes related to the conformity assessment procedure as they introduce simplifications for initial certification, recertification, and change management.
Specific inputs regarding breakthrough and orphan devices are covered in separate one-pager.

1 Background

The proposal provides targeted adjustments to the conformity assessment procedures under Art. 52 MDR / Art. 48 IVDR, particularly for products in higher risk classes. Annex VII “REQUIREMENTS TO BE MET BY NOTIFIED BODIES” lists further requirements and timelines for periodic reviews and changes.

The MDR/IVDR proposal shifts to a risk-based approach. The proposed targeted conformity assessment focuses on the device’s safety profile, state of the art, and relevant changes—rather than repeating a full assessment cycle at every periodic review and change assessment.

The MDR proposal also introduces the concept of Well-established Technologies (WET), allowing a reduced scope of review by notified bodies through sampling approaches instead of full technical documentation reviews and reduces sampling rates depending on the risk class.

2 Challenge

While in general the proposed risk-based conformity assessment procedures are strongly welcome, several elements remain unclear or insufficiently detailed:

> **Lack of clarity on scope of periodic reviews and changes**: Although the intention appears to be a focused review on changes rather than a full reassessment, the proposal does not explicitly define the process in regard to scope as well as needed actions. Annex VII (4.11) MDR/IVDR assigns responsibility for defining periodic review procedures/change assessments to NBs, risking inconsistent implementation across Europe.

- **Missing EU-level governance of sampling cycles:** The previous Art. 52(14a) MDR, which allowed the European Commission to issue implementing acts defining sampling frequencies and the sampling basis, has been removed without adequate replacement. Delegating this responsibility solely to NBs could increase variability and reduce harmonization.
- **Incomplete inclusion of Annex VII requirements:** The draft Annex VII published on 12 December 2025 (Ares(2025)11081575) contains additional provisions on timelines, reporting obligations, periodic review processes and change assessments. These aspects are only partially reflected in the MDR/IVDR proposal.

3
Solution

The proposed adjustments to conformity assessment procedures are fundamentally welcome. To ensure harmonized implementation and to maintain regulatory predictability, the following adjustments are recommended:

- **Clarification on framework conditions and scope** of periodic reviews and change assessment needed. These clarifications should be defined in an Annex VII delegated act with sufficient stakeholder involvement.
- **Reinstate Art. 52(14a) MDR** in its original form to ensure that audit cycle definitions remain harmonized at EU level rather than being determined by individual NBs.
- **Delegated Act of Annex VII** shall be aligned with MDR/IVDR proposal.

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MDR - IVDR Revision | Onepager | Structured Dialogue

April 2026

Introduction

Structured dialogue between Notified Bodies (NBs) and manufacturers has increasingly been recognized as a valuable mechanism to improve the efficiency and predictability of conformity assessment under the MDR/IVDR.
Even if a structured dialogue does not lead to a reduction in the overall timeline, it plays a crucial role in clarifying technical and regulatory expectations early in the process, particularly during the preparation of clinical investigations.

1 Background

The proposal under the MDR/IVDR reinforces the exchange between NB and manufacturers by requiring NB to establish documented procedures for conducting structured dialogues, which may take place both before and after the application process.

2 Challenge

To reinforce this practice, the legal framework governing structured dialogue between NB and manufacturers should be revised so that these discussions—while maintaining the independence and impartiality of NB – address not only the requirements that must be fulfilled but also the ways in which they can be achieved.

3 Solution

To enhance the outcome of such structured dialogue and thereof improving the efficiency and predictability of the conformity assessment while ensuring the impartiality of the NB, the following adjustments are proposed:

Reference Document	Adjusted text / summary of content
MDR / IVDR Annex VII Chapter 1.2.9 (additions are given in bold)	The requirements laid down in this Section in no way preclude exchanges of technical information, ~~**and**~~ regulatory guidance **and scientific advice** between a notified body and a manufacturer applying for conformity assessment. The notified body shall have documented procedures in place to offer and carry out dialogues with the manufacturer before

	and after an application for conformity assessment is lodged.
New MDCG paper on structured dialogue	**- Definition of the procedure** covering all steps from the initial offer to engage in a structured dialogue through to the documentation of the dialogue's outcome. - **Examples**—particularly those extending to study protocols and data analysis—include: (a) The overall **clinical** development strategy, encompassing proposals for clinical investigations and post-market clinical follow-up activities. (b) The relevance and adequacy of **non-clinical** testing strategies and plans, including bench testing, pre-clinical models, and usability assessments. - The **outcome of the structured dialogue** is not legally binding but should be duly considered by the Notified Body during the conformity assessment procedure. - The **impartiality of the notified body** during structured dialogues is ensured through a clear separation of responsibilities between the reviewer and the certifier within the organization of s notify body.

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MDR – IVDR Revision | One-pager | Access to notified bodies and fees

April 2026

Introduction

Access to Notified Bodies (NB) remains a key bottleneck for manufacturers within the MDR/IVDR system. The proposed fee reductions for micro and small enterprises, as well as manufacturers of orphan devices, are generally welcomed from the perspective of patients and innovation policy; however, without compensatory mechanisms, they pose significant risks to the industry.

1 Background

- NBs are organised as private-sector entities but fulfil governmental functions and responsibilities within the European market access framework for medical devices and IVDs.
- High and inconsistent fees place a particular burden on micro and small enterprises as well as manufacturers of orphan devices.
- The changes proposed in the MDR/IVDR revision include:
  - mandatory publication of all NB fees publicly and to the European Commission
  - Fee reductions (Micro ≥ 50%, Small ≥ 25%, Orphan Devices ≥ 50%)
  - Deferral of fees until the conclusion of the conformity assessment
  - 15-day response obligation for the NB to requests and applications
  - Right of intervention by the authorities to approve certain manufacturers in the public interest
- The aim is to create a fairer, more transparent and predictable fee structure to strengthen market access.

2 Challenge

Despite positive effects, the mandatory fee reduction is leading to margin pressure and investment barriers for NBs.

However, a stable, efficient NB sector is a prerequisite for secure market access, innovation and security of supply.

- There is a risk that NBs will **reduce their capacity** or **prioritise more lucrative applications** (in favour of more attractive procedures), which could further exacerbate capacity bottlenecks.
- Falling revenues could lead to **consolidation in the NB sector** and further exacerbate the structural bottleneck in the system.

> Without additional political or financial support, there is a risk that **access to NBs will become increasingly difficult for micro and small enterprises as well as manufacturers of orphan devices**, and that NBs will come under economic pressure.

3
Solution

Establishing a European funding mechanism

> Introduction of a *Union-wide central funding mechanism* in the form of an **EU financial equalisation scheme** or **fund** to compensate for NB revenue losses.

The European Commission shall ensure that funds are available to ensure the functioning and performance of the notified bodies and to guarantee the stable implementation of the conformity assessment procedures within the meaning of this Regulation.
Access to low-bureaucracy funding must be possible in parallel with the conformity assessment procedure.

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MDR - IVDR Revision | Onepager | WET

April 2026

Introduction

The introduction of the concept of *Well-Established Technologies (WET)* within the MDR revision represents a key element of the planned regulatory simplifications and simultaneously strengthens the risk-based approach. The aim is to appropriately regulate proven, long-established clinical technologies according to their risk, without compromising the high level of protection for patients. The introduction of the WET concept is fundamentally positive as it enables risk-based approach for proven technologies (see 1 Background).

1 Background

The introduction of the WET concept enables risk-based approach for proven technologies. With the MDR proposal, for the first time a legal definition of "Well-Established Technology Devices" is introduced in Art. 2 (72) MDR. The definition is largely based on the content of MDCG 2020-6 and is intended to be adapted through delegated acts and further specified by implementing acts (e.g., non-exhaustive lists of WET and non-WET products).

The existing implant-specific lists in Art. 18, 52 and 61 MDR are replaced by the WET term with the following exemptions:

> In Annex VIII MDR, classification rule 8 (8th and 9th indent) a reference to WET is added to the existing product list,
> In Art. 120 (3aa) MDR related to the transitional provisions, the existing product list is retained and not replaced by WET.

The following points are evaluated as very positive improvements and **should be maintained**:

> Implant Card (Art. 18 MDR): WET implants are exempt from the requirement for an implant card.
> SSCP (Art. 32 MDR): No more SSCP for Class IIb implants and Class III devices, as long as they are classified as WET.
> Clinical Evaluation / Clinical Investigation (Art. 61 MDR): The obligation for clinical investigation is eliminated for Class IIb implantable WET devices and Class III WET devices when sufficient data is available.
> Conformity Assessment (Art. 52 MDR): Reduced technical documentation review introducing the sampling approach for class III WET and class IIb implant WET, as well as reducing the amount of sampling from multiple reviews for generic device group / category to a single sampling file (class IIb non-implantable / class IIa)
> PSUR (Art. 86 MDR): no separate NB review for IIb implants and Class III, if WET.

2
Challenge

Distinction and Applicability: It is unclear whether the WET definition should apply to all risk classes or continue to be primarily intended for higher-class products (IIb/III).

The MDR proposal follows different approaches for implementing the WET term in the corresponding articles and classification rules (see above) leading to inconsistencies and having parallel product-specific lists and WET definition within the MDR.

The WET concept may not be restricted subsequently by any product lists which are issued as implementing act. Such lists could only be non-exhaustive examples of WET, resp. non-WET products.

3
Solution

While **highly welcoming the proposed approach of WET** to avoid regulatory uncertainties, it is recommended:

> to keep and apply the WET definition consistently across all relevant articles and risk classes,

> to harmonize existing product lists or completely replace them with the WET definition,

> to provide transparency regarding how the entries in the published implementing act on WET were compiled (WET lists).

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MDR - IVDR Revision | Onepager | Art. 10a

April 2026

Introduction

Article 10a was introduced with an amendment to MDR/IVDR (Regulation 2024/1860) and focuses on manufacturer obligations, requiring early notification of anticipated supply interruptions and discontinuations with regards to placing of devices on the Union market.
Due to unclear provisions and difficulties in implementation the article itself but especially the extension of the text is contrary to the overall aim of the MDR/IVDR revision which is simplification and decrease of bureaucracy. In particular because there is no effective measurement and action of the responsible Competent Authority.

1 Background

The use of terminology is shockingly wavering: the idea is to manage the consequences of shortages, but then its named interruptions and discontinuations of supply, and unavailability as a concept is introduced too so there are three different concepts that are supposed to mean the same thing.

The MDR/IVDR is made to “lay down rules concerning the placing on the market, making available on the market or putting into service of medical devices / in vitro diagnostic medical devices for human use and accessories for such devices in the Union”. Taking this purpose literally, Article 10a – neither the existing nor the proposed provisions -are covered by the purpose and intent of the MDR/IVDR.

2 Challenge

The **notification obligations** themselves are **still unclear and difficult to implement in practice**. In particular, it remains undefined which indicators should trigger the anticipation of a supply interruption and how manufacturers are expected to determine the relevant point in time. The wording “where not possible” in relation to the six-month advance notice requirement further increases legal uncertainty and invites divergent interpretations across Member States.

Section 4 introduces a new and not defined term “**unavailability**” within Art. 10a which is not connected with an interruption of supply. Also, the term and meaning of “**immediate risk of unavailability**” is not defined.

While an interruption of supply can lead to a shortage, affecting the availability of a specific product or even an entire product group supplied by multiple manufacturers, but in very rare cases result in

the loss of a therapy as there are other therapeutic options. However, **a shortage is a broader phenomenon and may arise from multiple causes** beyond supply interruptions of supply by the manufacture alone, including increased demand, regulatory constraints, or distribution challenges. Therefore, while supply interruptions are a key driver of shortages, they represent only one of several potential underlying factors.

In addition, the **proposed data infrastructure** in section 4 creates structural inefficiencies. Establishing a new IT system alongside EUDAMED risks duplication and inconsistencies and additional bureaucracy. Moreover, the system would combine fundamentally different types of information: manufacturer notifications of supply disruptions and user-level reports of shortages. These are not equivalent. Shortages at healthcare provider level may result from a variety of factors unrelated to supply interruptions, such as demand fluctuations or national reimbursement conditions. Consequently, the meaningful aggregation and interpretation of such data by competent authorities appears neither feasible nor reliable.

Particularly problematic is the requirement under paragraph 6 for manufacturers **to disclose sensitive and proprietary information on supply chains**, including production capacity and sales volumes. Such data are commercially confidential and strategically relevant. Requiring their disclosure in the absence of a public health emergency constitutes a disproportionate interference with business rights. It also raises concerns regarding data protection and potential access through freedom of information requests. Furthermore, this requirement can generally lead to finding suppliers willing to take this risk, which adversely affects the availability of devices and patient care. Finally the **enforcement vis-à-vis non-EU manufacturers remains questionable**.

At the same time and most important, the provision **does not equip competent authorities with adequate powers to act upon the collected information**. Simply gathering data on supply chain vulnerabilities does not ensure the availability of medical devices, especially in the absence of clear intervention measures or support mechanisms. The objectives stated in Recital 18—particularly ensuring availability and strengthening preparedness—cannot be achieved on this basis.

The **competence of HERA** according to Regulation 2022/123 is **limited to public health emergency scenarios, and not shortages** as such. The proposed text of article 10a basically creates a competence for HERA outside of public health emergency scenarios, because article 10a shortages that may harm patients are not immediately public health emergencies. Also, MDSSG is an entity intended to monitor supply and demand, while absence of user reporting makes it impossible under article 10a to have an idea of actual shortages. Paragraph 5 also completely disregards the amount of stock still in the supply chain.

Finally, the **role of industry and other key stakeholders** in developing the methodology for identifying critical devices is insufficient. Optional consultation does not reflect their essential expertise and operational responsibility.

The claimed efficiency gains and cost savings of the MDR/IVDR proposal are completely unconvincing. The proposed requirements are likely to impose significant and continuous administrative burdens on manufacturers, creating additional bureaucracy rather than reducing it.

3
Solution

Article 10a exceeds the scope and intent of the MDR/IVDR, imposes disproportionate obligations on manufacturers, creates duplicative system in addition to EUDAMED, and remains ineffective in achieving its stated objectives to ensure continuous patient care.

Against this background, the deletion of Article 10a is justified.

Before expanding the scope of the article, a thorough analysis of its necessity and proportionality must first be conducted, along with an impact assessment of the article's effectiveness and performance since its introduction.

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MDR - IVDR Revision | Onepager | Article 10(15) MDR Original Equipment Supplier

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Introduction

The MDR has significantly strengthened the responsibility of manufacturers through its requirements on technical documentation (Art. 10(4) MDR, Annex II MDR), while at the same time limiting established distributed manufacturing models, in particular OEM / private label and supplier structures. In practice, there is no clear regulatory framework defining how conformity can be demonstrated in such configurations without requiring disproportionate disclosure of intellectual property.
The European Commission's proposal to revise Article 10(15) MDR is therefore welcomed, as it aims to introduce legal clarity by allowing a structured allocation of technical documentation between manufacturers and third parties. The objective is to ensure legal certainty for all actors involved, while enabling a consistent and workable conformity assessment by Notified Bodies.

1 Background

The current Article 10(15) MDR is limited to the disclosure of the identity of third parties involved in design or manufacturing. The proposed revision introduces the possibility that parts of the technical documentation are drawn up and maintained by such third parties, while the manufacturer remains responsible for the remaining parts.

The revised wording also specifies that this applies in situations where a third party designs and manufactures the device.

The proposal further assumes that the complete technical documentation must be accessible for conformity assessment and supervision purposes, reflecting complex supply chain structures and existing transparency mechanisms, including EUDAMED.

2 Challenge

While the proposal is a positive step, the text currently lacks the level of clarity required for practical and consistent implementation. Key elements of the framework remain insufficiently defined. In particular, there is no clear specification of:

> the roles and responsibilities of the parties involved,
> the regulatory requirements applicable to third parties (e.g. quality management systems),
> the allocation and structure of technical documentation ("relevant" vs. "remaining parts"),
> the practical implementation of conformity assessment by Notified Bodies.

In addition, important procedural aspects remain unclear, including:

- whether and how Notified Bodies and authorities can directly access documentation and manufacturing sites of third parties,
- how consistency with Article 10(8) and Annex II MDR requirements is ensured,
- how contractual arrangements, access rights and auditability are to be structured in practice.

As a result, there is a high risk of divergent interpretations and continued legal uncertainty, potentially undermining the intended objective of the proposal.

3
Solution

To ensure that Article 10(15) MDR becomes a workable and legally robust framework, the objectives outlined in Recital 17 should be translated into a clear and operational provision, further specified to enable consistent and practical implementation.

This requires in particular:

- Introducing clearly defined roles (e.g. manufacturer and original equipment supplier, as reflected in Recital 17 MDR)
- Clarifying the structure and allocation of technical documentation (e.g. by reference to the relevant Annexes of the MDR)
- Defining minimum requirements for third parties, in particular regarding quality management systems
- Clearly specifying the role, access rights and assessment scope of Notified Bodies, including access to relevant documentation and manufacturing sites
- Clarifying inspection rights and responsibilities at the level of third parties
- Ensuring consistency with Article 10(8), Annex II MDR and EUDAMED transparency requirements
- Establishing clear requirements for contractual arrangements governing responsibilities, access rights and protection of intellectual property

In addition, it should be clarified that IP-sensitive documentation can be made available directly by the original manufacturer (design owner) to Notified Bodies or competent authorities, where appropriate, without requiring full transfer to the legal manufacturer.

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MDR - IVDR Revision | Onepager | Art. 17 Single-use devices and reprocessing of devices that are not for single use

April 2026

Introduction

Devices are developed and manufacture based on specific criteria. The selection of raw materials, the geometry, and the design determine whether a device is classified as a single-use device or a reusable product.
To request reusable devices by default only if not justified otherwise to increase the re-use of devices for economic and environmental reasons can lead to significant risk for patients.

1
Background

While we strongly welcome the introduction of harmonised, Union-wide rule Art. 17. A consistent regulatory framework across the EU/EEA is essential to ensure legal certainty, a level playing field, and high standards of public health protection.

But the primary and overriding principle must be patient safety. Patients must be able to trust that any medical device used in their treatment fully complies with the safety and performance requirements of the MDR. Reprocessed devices must therefore meet the same safety standards and rules as original devices placed on the market.

2
Challenge

Despite the overall objective, the proposed provisions raise several significant practical challenges:

> Technical Documentation Requirements

It remains unclear how a refurbisher can realistically compile a complete technical documentation file without access to original development data, clinical data, performance KPIs of the device. These elements are typically proprietary to the original manufacturer and are not accessible to third parties. This creates a structural gap between regulatory expectations and practical feasibility.

> Justification Requirements

The requirement to provide a justification for reprocessing introduces a potential substantial administrative burden, particularly because the concept of "justification" is not clearly defined and there is no harmonised methodology or criteria.

Additionally, there is a high risk of divergent interpretations by different Notified Bodies, leading to inconsistent assessments across the EU.

The expected lack of clarity and harmonisation directly **contradicts the stated objective of the revision text**, namely simplification of regulatory processes and reduction of administrative burden.

> Manufacturer Obligations and Evidence Requirements

Further clarification is needed regarding the exact scope of the refurbisher obligations and the type and level of evidence required to demonstrate compliance.

Without clear guidance, there is a risk of legal uncertainty and inconsistent enforcement.

3
Solution

To maintain high safety standards which ensure patient safety the following amendments of the MDR text are recommended:

Recital 21

The Commission Report on the operation of Article 17 of Regulation (EU) 2017/745 highlighted that the application of the rules on single-use devices is fragmented across the Union and the relevant requirements are complex to implement, resulting in a very limited and unattractive market for the reprocessing of single-use devices. ~~To simplify the rules regarding single-use devices and to increase the re-use of devices for economic and environmental reasons, it should be the responsibility of the manufacturer to determine whether and how a device can be reprocessed, based on the device's characteristics and properties. Unless the indication of single-use is duly justified by the manufacturer, devices should be subject to reprocessing,~~ whilst single use devices or devices which cannot be further reprocessed should be subject to full refurbishing.

Article 17: Single-use devices and reprocessing [new text]

(1) An indication that a device is for single use shall be based on the manufacturer's risk management documentation, where characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used shall be identified.

(2) If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n).

(3) Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device and must fulfil the obligations incumbent on manufacturers laid down in this Regulation, which

also include obligations relating to the labelling and traceability of the refurbished device in accordance with Chapter III of this Regulation. The refurbisher of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC. Indication of the refurbishing of a device and its traceability in relation to safe use shall be added to the product and delivered to the end user.

(4) The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single use devices.

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MDR - IVDR Revision | Onepager | Breakthrough and Orphan Devices Pathway

April 2026

Introduction

Regulatory barriers to market entry remain high for Breakthrough (BtX) and Orphan Devices (OD) as well as for innovative in vitro diagnostic medical devices. Within the ongoing revision of the MDR/IVDR, the European Commission proposes the introduction of specific and accelerated regulatory pathways supporting the objective of fostering innovation, while simultaneously ensuring timely access to life-saving medical technologies and in vitro diagnostic solutions for patient populations or those affected by rare diseases or pediatric populations. Industry therefore highly welcomes the proposed amendments. However, the effectiveness of these measures will depend to a significant extent on their consistent and efficient implementation.
A specific IVDR one-pager addressing regulatory pathways for orphan in vitro diagnostic medical devices complements this paper and outlines the particular needs for orphan IVDs under the IVDR framework.

1 Background

The proposal for the revision of the MDR/IVDR introduces, for the first time, legally robust provisions covering:

- Criteria for the definition of Breakthrough and Orphan Devices (Art. 52a(2) and (3)) MDR; Art. 48a IVDR;
- Specific conformity assessment pathways (Art. 52(14)(d) / 52a(9) and 52(15) / 52a(8)) MDR; Art. 48a IVDR, under which devices confirmed as Breakthrough or Orphan devices by an Expert Panel may benefit from accelerated assessments by Notified Bodies and, where appropriate, from reduced clinical data requirements.

2 Challenge

While the proposed introduction of a special pathway for BtX and OD under Art. 52a MDR/48a IVDR is highly welcomed, the following identified gaps may cause a delay for availability for EU patients.

No binding timelines for priority review: The proposal lacks binding timelines for priority review which leaves the accelerated pathway unpredictable for relevant stakeholders, such as: Expert

Panels, Notified Bodies, and manufacturers. Introduction through Implementing Acts would cause further delay.

Not recognizing next generation of same innovation: The proposal also fails to account for the fast pace of MedTech innovation, as the BtX or OD designation cannot be extended to subsequent generations of the same technology of the same manufacturer, even when next generations continue to fall within the definition of BtX or OD.

No defined specialized expertise or incentives for Notified Bodies: The proposal risks inconsistent scrutiny by not ensuring that Notified Bodies possess the required specialized capabilities and competencies for high-risk breakthrough devices, like disease area specialization and technical competencies. Furthermore, Notified Bodies might not take requests for evaluation of BtX or OD devices due to the additional pressure which the review of such devices may trigger.

3
Solution

To ensure the dedicated pathways under Article 52a MDR / 48a IVDR achieve their purpose, industry proposes three focused amendments:

Defined Timelines: Art. 52a MDR / 48a IVDR should introduce a fixed 120-day timeline (~50% of conformity assessment timelines as per Annex VII MDR as per Ref. Ares(2025)11081575) from application to (conditional) CE marking for breakthrough innovations This avoids delays associated with Implementing Acts.

Recognize next generation of same innovation: The new proposal should keep pace with MedTech innovations. Art. 52a MDR / 48a IVDR should explicitly allow the extension of the BtX or OD designation to subsequent generations of the same technology, when it continues to fall under the definition of BtX and OD.

Defined specific Notified Body expertise and ensure Notify Body support: Art. 39 MDR should introduce specific capabilities for Notified Bodies to perform (conditional) CE-marking activities as part of the newly established priority review for breakthrough technologies and emphasising capabilities and competencies required for Class III implantable devices. Definition of those NBs and obliging those designated NBs to take requests from BtX and ODs would provide certainty.

Specify risk-based approach: A risk-based approach is essential when evaluating medical devices intended for a limited number of patients in special clinical situations needs to be defined as per Art. 52(7) MDR. As a consequence, available clinical evidence may demonstrate safety and efficacy but only limited data on benefit. The term “limited clinical data” *should be specified as such.*

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MDR - IVDR Revision | Onepager | Classification of surgical instruments

April 2026

Introduction

The explanatory note (no. 29) of the EC legal proposal (2025-12) mentions that devices are classified in different classes depending on their level of risk. Some of the classification rules should be adapted to reflect the inherent risk of devices, resulting in a lower risk classification, such as for reuseable surgical instruments.

1 Background

The Commission proposal introduces targeted amendments to Rules 6 and 7 of Annex VIII MDR concerning surgically invasive devices for transient and short-term use.

In both rules, a new provision clarifies that reusable surgical instruments are classified as class I, regardless of the body part with which they come into contact.

The term “reusable surgical instruments” is defined in Annex VIII, Chapter III (Section 2.3) MDR.

2 Challenge

The proposed amendments are welcome as **they better reflect the inherent risk profile of surgical instruments** and remove the previous automatic link between classification and the anatomical site of use.

However, the proposal introduces a limitation that is not fully aligned with a consistent risk-based approach. The down-classification to class I applies only to reusable surgical instruments, but not to single-use surgical instruments. From a risk-based perspective, single-use surgical instruments should be classified in the same way as reusable surgical instruments, as both are intended for comparable clinical purposes.

Maintaining different classifications for these products therefore leads to a lack of consistency within the classification framework, as comparable devices are treated differently without a clear risk-based rationale.

3
Solution

To ensure a consistent and risk-based classification framework, the proposed amendment in Rules 6 and 7 should be adjusted as follows:

> Remove the limitation to “reusable” surgical instruments, so that the Class I classification applies to all surgical instruments, irrespective of reusability.
> Ensure that this adjustment is reflected consistently across the MDR framework, including Annex VIII (Section 2.3) and related conformity assessment provisions.

MDR EC legal proposal 2025-12	Stakeholder Proposal (2026-03)
Annex VIII 2.3. 'Reusable surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.	Annex VIII 2.3. ~~'Reusable~~ surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be**:** - reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out **or,** **- single-used on one individual during a single procedure;**
Annex VII 5.2. Rule 6 All surgically invasive devices intended for transient use are classified as class IIa unless they: – are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; – are reusable surgical instruments **regardless of the body part with which they come into contact**, in which case they are classified as class I; – are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; – are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb; – have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or – are intended to administer medicinal products by means of a delivery system, if such	Annex VII 5.2. Rule 6 All surgically invasive devices intended for transient use are classified as class IIa unless they: – are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; – are ~~reusable~~ surgical instruments **regardless of the body part with which they come into contact**, in which case they are classified as class I; – are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; – are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb; – have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or – are intended to administer medicinal products by means of a delivery system, if

administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.	such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.
Annex VII 5.3. Rule 7 All surgically invasive devices intended for short-term use are classified as class IIa unless they: – are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; – are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; – are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb; – have a biological effect or are wholly or mainly absorbed in which case they are classified as class III; – are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or ~~– are intended to administer medicines, in which case they are classified as class IIb.~~ **– are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;**	Annex VII 5.3. Rule 7 All surgically invasive devices intended for short-term use are classified as class IIa unless they: – are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; – are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; – are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb; – have a biological effect or are wholly or mainly absorbed in which case they are classified as class III; – are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or ~~– are intended to administer medicines, in which case they are classified as class IIb.~~ **– are ~~reusable~~ surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;**

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MDR - IVDR Revision | Onepager | Classification: Rule 11

April 2026

Introduction

The explanatory note (no. 29) of the EC legal proposal (2025-12) mentions that devices are classified in different classes depending on their level of risk. Some of the classification rules should be adapted to reflect the inherent risk of devices, resulting in a lower risk classification, such as for software.

1 Background

The Commission proposal for revising Rule 11 introduces a fundamentally different classification approach for software. While the current MDR sets Class IIa as the default classification, with specific criteria for up-classification to Class IIb or III and a broad residual category allowing classification as Class I, the proposal reverses this logic.

Under the proposed revision, software is classified as Class I by default. This default is then adjusted through a set of criteria defining when software should be up-classified to Class IIa, IIb or III, depending on the associated clinical risk.

This shift reflects an intention to better align classification with the actual risk posed by software and to enable lower classification where justified.

2 Challenge

The Commission proposal for revising Rule 11 draws conceptually on the IMDRF risk categorisation framework, an approach towards international harmonisation that is welcomed.

IMDRF assesses the risk of software as a medical device along two dimensions:

> the **significance of the information** provided for healthcare decision-making, distinguishing between to treat or diagnose, to drive clinical management, and to inform clinical management; and
> the **healthcare situation or condition**, distinguishing between critical, serious, and non-serious situations.

Importantly, according to IMDRF N12 (Section 5.1), all levels of significance of information (to treat or diagnose, to drive clinical management, to inform clinical management) are considered forms of

clinical management. This distinction is critical to ensure a consistent interpretation of the IMDRF framework and to avoid overextending the concept of clinical decision-making beyond regulated healthcare contexts.

However, this logic is not yet adequately reflected in the Commission proposal. In particular, the escalation criteria do not consistently incorporate the “to treat or diagnose” condition. As currently drafted, the third indent would result in any software used in a non-serious situation being classified as Class IIa, regardless of its actual role in clinical decision-making. This would, in practice, lead to an even stricter classification than under the current MDR.

Furthermore, the proposal does not sufficiently distinguish between clinical decision-making in a professional healthcare context and software intended for autonomous use by lay users. As a result, software intended solely for autonomous therapy management without requiring medical supervision (e.g. certain digital health applications) risks being systematically up-classified, which would contradict a risk-based approach.

To fully reflect the IMDRF concept, the escalation criteria should be systematically aligned with both dimensions, including the explicit integration of the “to treat or diagnose” condition, and further adjustments to accurately reflect the IMDRF matrix (as outlined in IMDRF N12).

In addition, newly introduced terms should be clearly defined within the MDR (e.g. in Annex VIII or through guidance), closely following IMDRF terminology. For example, IMDRF considers “to treat or diagnose” to apply where “immediate or near-term action” is required based on the software output.

3
Solution

Aligning Rule 11 with the IMDRF framework requires a clear and operational translation of its two core dimensions:

> The severity of the condition and the role of the software in clinical decision-making (treat/diagnose, drive, inform).
> A structured classification logic based on these parameters ensures consistent and risk-proportionate outcomes, supports international harmonisation, and enables the intended down-classification of software where justified.

To ensure consistent application and legal certainty, key concepts introduced in Rule 11 for **software classification** such as critical, serious, non-serious, treat or diagnose, drive clinical management, and inform clinical management **should be clearly defined within the MDR**, implementing regulation or guidance, closely aligned with IMDRF terminology.

We suggest amending Rule 11 as follows:

MDR EC legal proposal 2025-12	Proposal (2026-03)
Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I , unless the output is intended for a disease or condition	Software which is **a device in accordance with Article 1 (4) of this regulation** ~~intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition~~, is classified as Class I, unless its output is intended to address a disease or condition **in one of the following situations:**
– **in a critical situation with a risk of causing** death or an irreversible deterioration of a person's state of health, in which case it **classified** in class III; ~~or~~	– **To treat or diagnose by means of clinical management** in a critical situation**,** in which case it is class III
– **in a serious situation with a risk of causing** a serious deterioration of a person's state of health or a surgical intervention, **or to drive clinical management in a critical situation** in which case it is **classified** as class IIb or	– **To treat or diagnose by means of clinical management** in a serious situation, or to drive clinical management in a critical situation, in which cases it is class IIb
– **in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa.**	– **to treat or diagnose by means of clinical management** in a non-serious situation, to drive clinical management in a serious situation, or to inform clinical management in a critical ~~or serious~~ situation in which cases it is classified as class IIa

This would lead to the following classification schema:

State of Healthcare situation or condition	Significance of information provided by the Software in clinical management to healthcare decision-making		
	Treat or diagnose by means of clinical management	Drive clinical management	Inform clinical management
Critical	III	IIb	IIa
Serious	IIb	IIa	I
Non-serious	IIa	I	I

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MDR - IVDR Revision | Onepager | Orphan IVDs under the IVDR

April 2026

Introduction

In-vitro diagnostics (IVDs) play a crucial role in diagnosing, monitoring and treating rare diseases and very small patient populations. Many of these tests are used in very small volumes for conditions such as rare genetic diseases, rare blood groups for transfusions and tissue typing for transplantation, as well as for making specific therapy decisions. Without these diagnostics, many rare diseases would go undiagnosed or be mismanaged and mismatching of donor and recipient would occur.

The European Commission has proposed an amendment to Article 48a of the IVDR to improve the regulatory framework for orphan IVDs. This proposal is an important step towards ensuring the continued availability of diagnostics for rare diseases. However, it is essential that the orphan designation criteria are clear, practical and legally certain, to ensure that manufacturers can continue to provide such tests in the European Union.

1 Background

Diagnostics for rare diseases differ significantly from those for more common conditions. They are often developed for very small patient populations, which means they are associated with specific scientific, regulatory and economic challenges. From a scientific and clinical perspective, performance studies are often challenging due to the limited availability of patient cohorts. Generating extensive clinical evidence comparable to that for high-volume diagnostics is therefore often not feasible. From an economic perspective, these tests are typically produced and sold in very small quantities. The costs associated with IVDR compliance, including performance evaluation, quality management systems and notified body involvement, must be distributed over low sales volumes. This significantly limits the economic viability of such products. From a regulatory perspective, the IVDR introduced significantly higher requirements than the previous Directive, particularly regarding performance evaluation, clinical evidence, assessment of technical documentation and post-market surveillance. While these requirements are appropriate for high-volume and higher-risk devices, they may be disproportionate for orphan IVDs intended for very small patient populations.

Without a functioning orphan framework, there is a significant risk that manufacturers will discontinue such tests and will no longer introduce new orphan diagnostics to the European market.

2
Challenge

The key challenge lies in defining the orphan IVD framework in a targeted and practical way. If the criteria are too narrow or unclear, many diagnostics relevant to rare diseases may not qualify as orphan devices, meaning they would have to comply fully with standard IVDR requirements. This could make such tests economically unviable, resulting in them disappearing from the market. Two criteria are particularly important for a workable orphan framework:

Prevalence threshold: A prevalence threshold of 5 in 10,000 people, which corresponds to the established European definition of rare diseases and is already used in other EU regulatory frameworks, such as for orphan medicinal products. Using the same threshold would ensure regulatory consistency and legal clarity.

Absence of suitable CE-marked alternatives: orphan status should only apply where no suitable CE-marked alternative is available. However, 'suitable alternative' should not be interpreted purely formally. In practice, an alternative may exist, but it may not be equivalent in terms of clinical or technical performance or suitability for a specific patient subgroup. This is particularly relevant for rare genetic variants, rare blood groups, and highly specialised transplantation diagnostics, such as HLA.

If these aspects are not adequately reflected in the legislation, there is a risk that essential niche diagnostics serving very small patient populations will not qualify as orphan IVDs.

3
Solution

To provide **legal certainty** for manufacturers, notified bodies and competent authorities, a **clear and practicable definition is necessary** in Article 48a(3) of the IVDR.

The orphan framework should specifically target diagnostics for very small patient populations, ensuring that such tests remain available in the EU.

The combination of:

> a prevalence threshold of 5 in 10,000 and

> the absence of suitable CE-marked alternatives

,is an appropriate and proportionate approach. This ensures that the orphan framework is limited to genuinely rare conditions, while preventing important diagnostics from disappearing from the market due to excessive regulatory requirements.

Patient safety and performance requirements also remain in place, as orphan devices must still comply with the general safety and performance requirements of the IVDR. Therefore, the orphan framework does not reduce safety, but provides regulatory flexibility where standard pathways are not feasible due to very small patient populations.

Proposed legislative amendment (Article 48a IVDR)

The signing associations propose specifying Article 48a(3) IVDR as follows (new text in **bold**):

Article 48a – Orphan devices

A device shall be considered an orphan device where:

(a) the device is intended for the diagnosis, monitoring or management of a disease or condition that affects not more than **5 in 10,000 persons in the Union**, and

(i) **no suitable CE-marked alternative device is available on the Union market,**

or where available alternatives do not provide an equivalent level of clinical or technical performance for the specific patient population.

This clarification would ensure that diagnostics for rare diseases remain available in the European Union while maintaining a high level of patient safety and regulatory oversight.

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MDR - IVDR Revision | Onepager | IVDR “Active Ingredients” → “Critical Ingredients”

April 2026

Introduction

The Commission's proposal to revise the IVDR replaces the term 'active ingredients' with 'critical ingredients'. While this change appears to be primarily terminological, it could have significant practical consequences. Notably, it could necessitate amendments to labels, instructions for use, and technical documentation, even when the product itself remains unchanged. This could result in a disproportionate regulatory burden, global re-registration requirements, supply chain disruption and avoidable environmental impact.

1 Background

The proposed change replaces the term 'active ingredients' with 'critical ingredients' in the IVDR. This shifts the focus from substances that contribute to the intended purpose of the device to components that are essential for its performance. Consequently, more components may need to be described in the instructions for use and technical documentation. Although the change is intended as a clarification rather than a substantive change, it may still require updates to labels, instructions for use (IFUs) and product documentation, even if the device itself, its composition, performance and safety remain unchanged.

2 Challenge

In many countries worldwide, changes to labels or instructions for use can trigger regulatory actions, such as notifications, variations, amendments or new registrations. Therefore, a change in the terminology used in EU legislation could have global downstream regulatory consequences. Despite no change to the product itself, manufacturers may be required to update registration dossiers and submit variations in multiple jurisdictions. Such regulatory consequences would be disproportionate to a purely terminological change. Additionally, global label changes would necessitate updates to packaging materials, printed IFUs, logistics processes, and existing inventory. In markets requiring prior approval, products may only be placed on the market after the label change has been approved, which could result in delays and temporary supply interruptions.

Furthermore, replacing packaging and printed materials on a global scale would generate unnecessary waste and increase transport requirements and CO_2 emissions. Therefore, a purely terminological change could result in significant administrative, logistical and environmental burdens without improving product safety or performance.

3
Solution

Replacing the term 'active ingredients' with 'critical ingredients' should be clearly defined as a terminological clarification that does not automatically necessitate changes to labels, instructions for use or registrations, provided the device's composition, intended purpose, performance and safety remain unchanged.
Corresponding clarifications in legal texts or guidance would prevent an unnecessary regulatory burden, avoid the need for global re-registration processes, reduce environmental impact, and help ensure the continued availability of in vitro diagnostic devices.

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MDR - IVDR Revision | Onepager | Routine Blood Draws in IVDR Performance Studies

April 2026

Introduction

The European Commission's proposal to simplify the MDR and IVDR aims to reduce the regulatory burden, facilitate innovation, and improve market access for medical diagnostics. In this context, the Commission has proposed changes to the requirements for clinical performance studies. However, a key regulatory issue remains unresolved concerning routine blood sampling in performance studies under Article 58 of the IVDR.

The current wording, which refers to 'additional invasive procedures', creates legal uncertainty over whether routine venous or capillary blood collection can be considered one such procedure. This uncertainty could result in low-risk performance studies being subject to the full regulatory approval process, which would contradict the objective of simplifying and accelerating clinical research in Europe.

1. Background

Routine blood collection is one of the most common medical procedures worldwide, with trained healthcare professionals performing it millions of times every day. Venous and capillary blood samples are the primary sample types used in in-vitro diagnostic (IVD) testing and therefor form the basis of the vast majority of IVD performance studies. From a medical perspective, routine venous and capillary blood collection is considered a low-risk procedure. Any possible complications, such as minor haematomas or temporary circulatory reactions, are rare and can be effectively managed by trained personnel using standard medical procedures.

The main types of blood collection are:

> Venipuncture (venous blood collection)
> Capillary blood collection (e.g. finger prick)
> Arterial blood collection, which is less common and associated with higher risks

Most IVD performance studies rely on venous or capillary blood samples because these are the standard sample types used in diagnostic practice.refore form the basis of the vast majority of IVD performance studies.

2
Challenge

The IVDR does not clearly distinguish between surgical procedures and routine invasive sampling procedures, such as standard blood tests. Consequently, routine blood collection could be deemed an 'additional invasive procedure' under Article 58 of the IVDR. This creates a regulatory conflict. On the one hand, routine blood draws are low-risk and standard medical practice. However, if they are interpreted as additional invasive procedures, performance studies involving such routine sampling would be subject to the full application and approval procedures.

This would have several consequences:

> significant delays in study approvals;
> increased administrative burden for sponsors and authorities;
> increased costs for performance studies;
> particular challenges for small and medium-sized enterprises;
> risk that performance studies will be conducted outside the EU instead.

Performance studies are a central element in the development of new diagnostics. Delays in study initiation directly affect innovation cycles and patient access to new diagnostic tests.

3
Solution

There are already extensive protection mechanisms in place for study participants, which apply independently of any additional regulatory approval procedures. Every performance study is subject to review by an ethics committee, which considers the scientific relevance of the study, the risks to participants, the volume and frequency of blood collection, and the protection of vulnerable groups. This review takes place irrespective of the regulatory pathway and ensures that the rights, safety and well-being of participants are protected. Additionally, international standards such as ISO 20916 outline detailed requirements for the design and execution of performance studies, including provisions regarding patient safety, informed consent, data quality, and scientific validity.

Stricter regulatory requirements remain fully justified where performance studies involve increased risks for participants. Examples include surgical sampling procedures such as tissue biopsies, cerebrospinal fluid collection and arterial blood sampling; studies involving vulnerable populations; and studies involving unusually large blood volumes.

However, routine venous or capillary blood collection, when performed according to standard medical practice, should not automatically trigger the full regulatory requirements for interventional performance studies. A clear, risk-based distinction is therefore necessary in Article 58 of the IVDR. Performance studies should only fall under Article 58 where additional invasive procedures present a relevant clinical risk beyond that associated with routine blood collection.

Proposed legislative amendment (Article 58 IVDR)

The signing associations propose clarifying Article 58 IVDR as follows (new text in **bold**):

Article 58 – Performance studies

This Article shall apply to performance studies involving **additional invasive procedures that present a risk to the subject beyond that associated with routine venous or capillary blood collection performed in accordance with standard medical practice.**

Routine venous or capillary blood collection shall not, in itself, be considered an additional invasive procedure within the meaning of this Article, unless the volume or frequency of sampling presents a significant risk to the subject.

This clarification would ensure a proportionate, risk-based regulatory approach while maintaining a high level of patient safety.

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