MedicalMountains

Towards MDR 2.0: Further Proposals for proportional regulatory Reforms to ensure Availability of essential Medical Devices

POSITION STATEMENT

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Towards MDR 2.0: Further proposals for proportional regulatory reforms to ensure availability of essential medical devices

Tuttlingen, June 2025

Kindly note: The order in which proposals are presented does not imply any prioritization. Recommendations from earlier papers[1] remain applicable and are only elaborated upon here if supplemented by new reasoning or explanatory context.

[1] MedicalMountains suggestions MDR 202407_EN.pdf from July 2024 and "Urgent need for action: Legal short-term measures to facilitate MDR/IVDR implementation in Q1 2025", signed by 17 associations from December 2024

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About MedicalMountains

MedicalMountains GmbH was founded in 2010 as a regional cluster management organization in Tuttlingen, the “world centre of medical technology”. Europe's largest MedTech cluster unites more than 400 manufacturers, suppliers, and service providers. This direct proximity to industry enables MedicalMountains to act in a needs-oriented and practical manner. The aim is to connect and strengthen all players in the medical technology sector. No distinction is made in terms of company size; large enterprises are just as much a part of the network as small artisan businesses. However, the main focus is on supporting SMEs, which form the backbone of the industry.

The shareholders of MedicalMountains come from the regional public sector, the guild for surgical mechanics and institutes for research and science. MedicalMountains has always been a neutral, independent, and self-financed organization. It’s field of activity extends far beyond regional borders to national and international level. Support for the partners is usually provided in a cooperative approach with medical device manufacturers, suppliers, research institutions, healthcare professionals, experts from consulting and services and representatives from politics or authorities.

Medical Mountains acts according to the principle of “push and pull”. It is pulled by the needs of the industry and takes up its issues and concerns, be they of a technical, regulatory, or political nature. At the same time, it pushes the companies into forward-looking fields so that their opportunities can be recognized and exploited. This is reflected in the service resorts of MedicalMountains GmbH: “Expanding specialist knowledge”, “Representing interests”, “Supporting implementation”, “Increasing visibility” and “Enhancing innovative strength”.

CONTENTS

1 CONTEXT & PURPOSE OF THIS PAPER

This paper complements previously submitted position papers[2] and further develops key regulatory proposals aimed at improving the Medical Device Regulation (Regulation (EU) 2017/745, MDR).

Its purpose is threefold:

- to provide decision-makers with a clear understanding of the structural root causes behind current supply constraints.
- to put forward concrete and industry-supported proposals for regulatory simplification.
- to contribute constructively to upcoming implementing or delegated acts, a targeted MDR 2.0 review, or a practical omnibus solution.

The overarching goal is to reduce administrative and bureaucratic burdens — without compromising patient safety at all — thereby ensuring continued access to essential medical devices and medical innovations for patients in Europe.

Kindly note: The order in which the following proposals are presented does not imply any prioritization. Recommendations from earlier papers[2] remain applicable and are only elaborated upon here if supplemented by new reasoning or explanatory context.

Since the MDR entered into force in May 2021, the availability of both established and innovative medical devices in the EU has significantly declined. This was clearly evidenced by the 2023 industry survey conducted by the German Chamber of Industry and Commerce (DIHK), MedicalMountains, and SPECTARIS[3].

Despite some regulatory improvements, many key root causes for product discontinuation — even for routine and established products — and the migration of innovation persist:

1. Lack of predictability and planning certainty in the conformity assessment process.
2. Excessive and often unnecessary regulatory requirements.
3. Disproportionate resource burden relative to the expected product revenue.

These challenges particularly affect SMEs, jeopardise the availability of essential legacy and niche products, and undermine Europe's innovation capacity.

While the MDR rightfully aims for high safety and performance standards, its practical implementation falls short:

- More documentation does not automatically lead to higher product safety.
- Requirements are inflated by misalignment between legislative and sub-legislative acts and by insufficient use of existing data (historical data, replicated content).
- Even long-established safe products with stable designs and manufacturing processes are forced to generate new data unnecessarily.
- Low risk, tool-like medical devices with only indirect clinical benefit are not appropriately addressed, resulting in legal uncertainty as to appropriate intended purpose specifications, clinical evaluation strategies on the basis of non-clinical data and, in the absence of direct causal relationship to observable clinical endpoints, often disproportional expectations regarding the provision, quantitative analysis and interpretation of clinical safety and performance data.

[2] MedicalMountains suggestions MDR 202407_EN.pdf from July 2024 and "Urgent need for action: Legal short-term measures to facilitate MDR/IVDR implementation in Q1 2025", signed by 17 associations from December 2024
[3] https://medicalmountains.de/survey_mdr_2023

The fact is: As it is, the current framework is not achieving policymakers' original objectives. The result: Innovation is stifled, and supply continuity is threatened.

A growing number of MDCG guidelines and divergent interpretations across member states and notified bodies further worsen the situation, creating unfair market conditions. What the sector urgently needs is legal certainty and predictability.

We therefore strongly support current EU initiatives, including:

- Implementing regulation for electronic instructions for use for medical devices
- Establishment of an expert panel on orphan and pediatric devices
- Expansion of the list of well-established technologies
- Reclassification of well-established technologies
- Implementing rules regarding requirements to be met by notified bodies

Moreover, we welcome the ongoing evaluation[4] of MDR/IVDR which provides an important opportunity to assess whether the frameworks are effective, efficient, whether they meet current and future needs, are consistent with other measures, and provide EU added value.

We contribute to this process by offering pragmatic proposals for the ongoing MDR revision as well as for supporting short-term legislative measures. While the reform of the MDR is now in motion, it will inevitably take time — time that patients and manufacturers simply do not have. That is why we strongly advocate for the timely use of delegated and implementing acts to enable faster, targeted improvements wherever feasible.

All proposals in this paper are built on two essential pillars:

1. They are supported by both small and large manufacturers — including those who have already certified all their products under the MDR.
2. They are fully aligned with high safety and performance standards — we propose eliminating only requirements which do not add value for patients or users, but burden manufacturers and notified bodies unnecessarily.

At MedicalMountains, our guiding philosophy and goal is not simply to point out problems, but to offer solutions:

- Explanatory: providing context for why these proposals are necessary.
- Constructive: contributing to a smarter, more proportionate, and more resilient regulatory system.

Ultimately, this is about much more than regulatory processes — it is about preserving a culture of innovation, securing Europe's leadership in medical technology, protecting jobs and enhancing economic resilience. But most importantly, it is about ensuring patient access to high quality care by making available safe and effective medical technologies.

[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en

2 FUNDAMENTAL REGULATORY FLAWS

Despite its high-level objectives, the current MDR framework contains three structural weaknesses that directly threaten the availability of essential medical devices, stifle innovation, and undermine legal certainty:

1. It lacks differentiated regulatory pathways for devices with only indirect clinical benefit, leading to disproportionate evidence requirements and market barriers for technologies essential for day-to-day clinical practice but unsuited to indication-specific evaluation based on clinical evidence.
2. It suffers from terminology gaps and inconsistencies, which result in significant interpretation disputes, legal uncertainty, delays in market access, and divergence from international standards and benchmarks.
3. It fails to define the role of health care providers and clinical professionals as relevant stakeholders in providing safe and effective patient care by ensuring appropriate education, training and safe device use, thus creating unrealistic documentation and liability expectations on the side of manufacturers, and inefficiencies in the regulatory system.

Addressing these flaws is critical to restoring proportionality, safeguarding patient access, and ensuring a resilient European MedTech ecosystem.

2.1 LACK OF DIFFERENTIATED PATHWAYS FOR DEVICES WITH INDIRECT CLINICAL BENEFIT

The current MDR framework and related MDCG guidance documents borrowed selectively from pharmaceutical regulations, implicitly assuming that (most) medical devices function analogously to pharmaceuticals. It is taken for granted that there is always a direct causal relationship between using a medical device and observable patient outcomes, and that they are thus capable of directly preventing, treating or diagnosing specific conditions. Therefore, it is expected that their intended use is linked to specific patient populations, clinical indications and outcomes, including clinical benefits. While true for certain types of medical devices like pacemakers or artificial joints, this approach fails for a broad category of procedure-enabling, tool-like devices with only indirect clinical benefit. This category of medical devices includes but is not limited to surgical tables, device carts, trays, tables, light sources, passive surgical instruments and tools, high-frequency surgical instruments, surgical power systems and application parts, endoscopes, sheaths, obturators and endoscopic instruments, perfusion pumps and tubings, cannulas, catheters, laser fibres, connectors and medical device accessories.

Such devices:

- Have no diagnostic or therapeutic effect on their own. They are intended to be used in combination with other products and medical interventions to enable clinical procedures, tailored to patient-specific needs as determined by the professional user. Achieving clinical success and meaningful patient benefit depends on a complex interplay of factors — including patient characteristics, user experience, all medical products and interventions used in a treatment episode, the healthcare setting, and care processes. All these elements collectively influence the actual patient benefit and measurable clinical outcomes. Beyond reports on device failures, it is neither possible nor scientifically or ethically justified to experimentally determine if and to what extent individual medical devices with only indirect clinical benefit contribute to an observable, patient-relevant safety or efficacy endpoint or

clinical benefit. A proof of causality and quantification of effect sizes would require randomized controlled clinical investigations using sham-surgery in control groups. This is neither feasible, nor ethically justifiable.

- Are mostly tool-like multi-use, generic devices with simple designs and modes of action, which often are part of multiple different procedural setups, specified according to the training, experience and preferences of the professional users. Therefore, no specific medical indication or patient population can be attributed to these products by manufacturers beforehand.
- Derive their clinical utility from their technical and anatomical function in enabling treatment pathways, with safe and effective use depending on the clinical training, experience, and judgment of the healthcare professional, and any achievable patient benefit depending on a multitude of further variables.
- Their performance depends on metrical specifications, interoperability with other products, and technical safety demonstrated through preclinical methods (electrical, biological, physical, chemical).

This can be illustrated by the example of a surgical hammer used in orthopaedic procedures. On its own, the hammer has no clinical benefit; it serves no purpose as a stand-alone instrument. Its intended use becomes meaningful only as part of the surgical instrumentation — for example, to implant a hip stem. Similarly, it is virtually impossible to define a clinical intended purpose for the hammer in isolation or to demonstrate any clinical benefit through a standalone clinical evaluation or study.

Despite this, Article 61 MDR and related guidance still require manufacturers to demonstrate clinical safety, performance and benefit based on clinical evidence as if a direct, causal link to the quality of care and observable endpoints existed. This leads to:

- Unrealistic expectations for generating clinical data across countless use cases and indications, posing significant burden and unresolvable ethical challenges on health care providers and manufacturers.
- Inconsistent interpretation by notified bodies.
- Excessive regulatory burden.
- Market withdrawal of essential products.
- Threats to supply security, particularly for niche and paediatric applications with inherently limited data.

To address this, the MDR — including Article 2 (Definitions), Article 61 (Clinical Evaluation), Annex I (General Safety and Performance Requirements), Annex XIV (Clinical Evaluation), and related MDCG guidance — should be revised to explicitly account for medical devices with indirect clinical benefit. We propose:

- Clear definition of devices with only indirect clinical benefit and no causal, quantifiable contribution regarding observable performance, safety and benefit patient outcomes. Formally recognize this device category.
- Align clinical evaluation expectations with actual device function and use, focusing on technical performance and usability in supporting a medical procedure rather than a direct therapeutic outcome.
- State in Article 61(10) that medical devices with only indirect clinical benefit are exempted from the need to provide clinical performance and safety data for the substantiation of general safety and performance requirements due to scientific and ethical constraints.
- Clarify in Article 61 and Annex XIV that the absence of an indication-specific and patient-population specific intended purpose precludes specific clinical safety and performance endpoints (are not applicable).

- Recognize that such devices' safety and performance, due to their mode of action and intended use, are best demonstrated through technical and design verification and usability evaluation, not clinical investigations.

Without these adjustments, patient access to essential devices will continue to erode — to the detriment of both patient care and European competitiveness.

2.2 GAPS AND INCONSISTENCIES IN TERMINOLOGY

Terminology gaps and inconsistencies — particularly regarding "intended purpose" vs. "intended use" — undermine legal certainty and harmonisation across the MDR, MDCG guidance, as well as across EU language versions.

Consequences are:

- Diverging interpretations among notified bodies, competent authorities, and manufacturers.
- Missing and ambiguous definitions complicate technical documentation and clinical evaluations, leading to delays in CE marking and market access due to prolonged discussions with Notified Bodies.
- Ambiguous terms such as "intended purpose" directly affect device classification and conformity assessment pathways, increasing the risk of non-compliance and reducing system efficiency. According to BSI[5] conformity assessment under the MDR depends on "intended purpose" and device classification. However, current ambiguities make correct classification and route selection uncertain, increasing compliance risks.
- SMEs and innovators are disproportionately affected, as they lack the resources to manage these complexities. In this way, terminology inconsistencies become a direct barrier to innovation.
- Patient care also suffers. Delayed conformity assessments postpone patient access to innovative or life-saving devices. Additionally, regulatory uncertainty forces some manufacturers to withdraw products from the EU market, reducing treatment options.
- At the international level, inconsistent MDR terminology conflicts with globally accepted standards (ISO 14971, IMDRF guidance), complicating global submissions and hindering mutual recognition of conformity assessments — negatively impacting trade and competitiveness.

Additional examples of harmful gaps and terminology inconsistencies are:

1. "Incident" vs. "Serious Incident"
   Inconsistent interpretation of "serious deterioration in health", despite MDCG 2023-3 Rev.2[6].
2. "Medical Device Lifetime"
   Undefined in the MDR, leading to diverging expectations for safety, performance demonstration and post-market surveillance planning.
3. "Custom-Made Device"
   Ambiguity between custom-made, patient-matched, and adapted mass-produced devices (Article 2(3)), causing inconsistent classification.
4. "Accessory for a Medical Device"
   The broad definition in Article 2(2) creates confusion as to whether software, apps, or components qualify as accessories or standalone devices — impacting classification, conformity assessment, and labelling requirements.

[5] Medical Device Lifetime - BSI
[6] MDCG 2023-3 Rev.2 - Q&A on vigilance terms and concepts

5. "Residual Risk"
   Annex I (4) requires disclosure of "any residual risks", whereas ISO 14971 requires disclosure of significant residual risks — leading to over-documentation and disputes with Notified Bodies The broad definition in Article 2[7] creates confusion as to whether software, apps, or components qualify as accessories or standalone devices — impacting classification, conformity assessment, and labelling requirements.

To resolve these issues and restore regulatory clarity and legal certainty, the following actions are required:

- Create a binding central glossary of MDR terms and definitions in all EU languages aligned with internationally recognized standards (e.g. ISO 14971, IMDRF guidance).
- Clarify "intended purpose" vs. "intended use". We propose:
  - Intended Purpose: Principal intended clinical benefit of the device.
  - Intended Use: Broader clinical context, including indications, contraindications, and intended user environment.
- Introduce standardised templates for consistent documentation.
- Re-evaluate and update MDCG guidance with regards to consistent terminology, and train Notified Bodies and Competent Authorities for consistent interpretation.

Regulatory certainty and terminology alignment (also with international standards) must be a top priority in the forthcoming MDR revision process.

2.3 Lack of defined role for health care providers & clinical professionals in ensuring safe use of medical devices

For procedure-enabling devices and well-established surgical instruments, safe use and effective patient treatment fundamentally depends on:

- Professional education and continuous training of users.
- Clinical judgement.
- Surgical technique.
- Adequate infrastructure and healthcare environment

It is generally accepted that healthcare provision strongly depends on the expertise and experience of the healthcare professionals involved. This relationship is well known from the "learning curves" in surgery, where training of new surgical procedures requires certain case numbers until a steady-state of surgical- and patient-outcome is achieved. Also, the case mix and case volume of a healthcare provider often correlates with the quality of care. The safety and effectiveness of interventions using procedure-enabling devices therefore is strongly affected by the clinical use setting.

The MDR, however, assigns full responsibility and documentation burden for clinical safety and performance to manufacturers — an unrealistic expectation for devices whose safe use is inherently determined by the user, and observable clinical outcomes are largely depending on patient factors and the healthcare setting. Manufacturers can and must ensure technical product safety (mechanical, biological, chemical), but cannot reasonably assume liability for clinical use, technique and interventional outcomes.

[7] MDR Article 2 - Definitions - Medical Device Regulation

For example, in the case of a simple surgical hook used in brain surgery, the inherent risk does not stem from the instrument itself, but from the sensitive nature of the tissue being operated on.

The consequences of current regulations are, that Notified Bodies increasingly demand using quantifiable clinical outcomes to be used for the evaluation of safety and performance of procedure-enabling devices, and the inclusion of "generally known" surgical risks in IFUs — even for standard instruments — despite the fact that surgical risk is determined by technique and clinical context, creating:

- False causal relationship between individual devices and procedural risks.
- Confusion in responsibility allocation regarding quality-of-care provision and patient information.
- Administrative overload,
- Legal uncertainty.
- No added patient safety.

The MDR must be revised to:

- Establish a shared responsibility model between manufacturers and healthcare providers/ professional users.
- Recognise that safe and effective use of well-established surgical instruments and procedure-enabling devices with indirect clinical benefit is primarily the responsibility of healthcare providers and trained healthcare professionals.
- Encourage continuous professional education and clinical training of healthcare professionals as part of the overall safety framework.
- Enable an EU-wide simplified feedback mechanism and data platform for leveraging clinical routine data for both, quality of care evaluation and medical device post-market surveillance including post market clinical follow-up.

Without addressing this legislative gap, the MDR risks fostering a "responsibility vacuum" with unrealistic expectations on manufacturers and unacknowledged clinical responsibility on the healthcare professional side that undermines both safety and innovation.

3 TARGETED REFORM PROPOSALS

Based on the structural flaw outlined above and further empirical values from practice, we propose the following targeted amendments to restore proportionality and legal clarity into the MDR.

3.1 REDUCE UNNECESSARY CLINICAL DATA REQUIREMENTS

Proportional clinical evidence increases patient safety. It is a fundamental misconception that mandating clinical data for all products automatically enhances patient safety. For low-risk and well-established medical devices, this is demonstrably false — and may even have the opposite effect:

Patients suffer from the absence of safe and effective products — not from a "lack of clinical data" on product designs and products already proven safe in millions of uses often over decades. If such products are withdrawn due to disproportionate regulatory data generation efforts and costs, patients face suboptimal or even unavailable treatment options — a direct threat to the health of those in need. Also, healthcare providers face unrealistic demand from manufacturers for generating clinical data for routine products without generating meaningful new information. This poses ethical challenges and withdraws scarce resources from patient care and conducting meaningful research. In this context, the benefit-risk balance is crystal-clear: the benefit of maintaining access to established devices far outweighs theoretical risks of using products with decades of safe use.

In a proper benefit-risk evaluation, the risk to patient health caused by product unavailability must be weighted at least as heavily as technical product risks. Smart, proportional clinical requirements ensure continued access to proven, safe devices — which directly protects patient safety.

3.1.1 Reframing and expanding the "well-established technologies" concept towards a criteria-based approach for all risk classes

Proposal / Amendment:

The MDR should not only extend the concept of well-established technologies (WET) to additional device classes (Class I, Ir, Im, Is, IIa, and IIb non-implantables), but reconceptualize the concept entirely.

It should allow all medical devices of all risk classes to be WET, provided:

- they meet the criteria defined in section 1.2 of MDCG 2020-6[8]:
  - relatively simple, common and stable designs with little evolution
  - their generic device group has well-known safety and has not been associated with safety issues in the past
  - well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art
  - a long history on the market.
- they have an established mode of action, a mature design and manufacturing process, and are considered standard of care products in the respective medical field.
- they can - along with similar types of devices - be considered part of a generic device group, which – as a group - has a long-standing market presence (e.g. ≥ 5 years).
- they show consistent post-market safety (no FSCA or serious trends).
- they fulfil applicable harmonized standards (if applicable).
- little new clinical insight would be expected from additional clinical studies.

However, instead of relying on static, soon-obsolete product lists, the regulation should introduce durable, criteria-based definitions of WET — ideally through Common Specifications (CS) — which reflect technological maturity, market experience, and safety profile. Such a shift would provide a forward-compatible, legally reliable framework for both current and future devices and materials.

Concrete suggestions are:

- Amend Articles 61(6) and 61(8) to introduce a new paragraph covering non-implantable Class I–IIb medical devices under revised WET conditions.
- Replace product-based lists with a permanent, dynamic set of eligibility criteria via Common Specifications (CS).
- Use delegated acts to expand and update those CSs and reflect evolving standards and material knowledge.
- Allow reference to WET status under Article 61(10) as sufficient justification for clinical data waivers and reduce requirements for usability data.

Justification:

Current MDR exemptions for WET (Article 61(6b) and 61(8)) are:

- restricted to class IIb implantables and class III devices.

[8] https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_6_guidance_sufficient_clinical_evidence_en_0.pdf

- restricted to various, inconsistent types of medical devices without obvious rationale for their selection.
- vaguely worded and inconsistently interpreted, lacking clear criteria or practical applicability.

Yet, the rationale for the WET concept applies equally — or even more so — to standardized passive and active lower-risk devices such as scissors, forceps, clamps, chisels, hammers, retractors, probes, kidney dishes, drape clamps and similar routine instruments. These:

- have a long safety track record, often spanning decades or in similar designs even centuries.
- are present in every hospital and in daily use.
- are based on mature mode of action, designs and well-understood materials (e.g. stainless steel).
- offer no plausible clinical innovation potential.
- lack published clinical studies and incentives for generating new clinical data in clinical studies.

Even where clinical studies have been carried out, no new scientific insights are expected. For example, which new or additional clinical insights are expected for a simple tool like a scissor or retractor? Similarly, it is unclear, which additional insights could be achieved by usability studies, for such well-established and daily used surgical instruments. For that reason, other legislations have implemented less burdensome approaches for similar types of devices.

Furthermore, as the equivalence principle under Art. 61(5) is de facto non-functional due to impractical contractual access requirements between competitors - in the absence of workable equivalence - a clear, criteria-driven and legally binding WET framework expanded to all risk classes and operationalized is the best solution.

By maintaining full clinical evidence, sampling and post market surveillance expectations, the MDR places an unjustified burden on manufacturers, especially SMEs — ultimately driving such products out of the market.

Conclusion/Expected benefits:

A sustainable criteria-based expanded WET-system to all risk classed avoids premature obsolescence of regulatory definitions. It preserves access to critical routine devices and basic surgical tools. It prevents unnecessary market exits, especially among SMEs, aligns EU framework with international regulatory benchmarks (e.g. FDA 510(k), China NMPA Article 34), improves legal clarity and planning certainty for manufacturers, and allows authorities to focus regulatory resources on genuinely high-risk or innovative products.

3.1.2 Proportional clinical evidence requirements for legacy low-risk devices

Proposal / Amendment:

Article 61 MDR shall be amended to eliminate the requirement for a Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER) for legacy devices in Classes I, I* (Ir, Is, Im), and selected non-active Class IIa devices with a proven safety record.

Minimum requirements for demonstrating clinical safety and performance may be specified in common specifications:

1. **Scope**
   - Applicable to Class I, Ir, Is, Im, and non-active Class IIa devices.
   - Device must have been marketed in the EU for ≥ 5 years.
   - No serious incidents or field safety corrective actions in the previous 5 years.
2. **Clinical Safety Demonstration**
   - Manufacturers may fulfil Article 61 MDR requirements without a full CER if they provide:
     a. Declaration of absence of serious incidents resulting from the product (based on PMS data).
     b. Evidence of compliance with state of the art (e.g. ISO standards, harmonised norms).
     c. Documented long-term safety through PMS, sales, and complaint data.
     d. Valid preclinical evidence:
        • Biocompatibility testing (ISO 10993)
        • Mechanical/functional testing
        • Reprocessing validation (if applicable)
3. **Documentation – Legacy Safety Summary File (LSSF)**
   - Manufacturers shall maintain a Legacy Safety Summary File containing:
     a. Product description and classification.
     b. Risk management report (ISO 14971).
     c. Post-market surveillance (PMS) summary for ≥ 5 years.
     d. Declaration of conformity with relevant standards.
     e. Test reports (biocompatibility, mechanical, reprocessing/sterilisation as applicable).
     f. State-of-the-art alignment and justification for clinical safety**.**
4. **Exclusions**
   - This exemption does not apply to:
     a. Devices with significant design or material changes in the last 5 years affecting safety/performance specifications or mode of action.
     (Changes such as labelling without safety impact are excluded from this exclusion.)
     b. Devices with emerging new risks or safety signals.
     c. Devices with new indications or patient groups.
5. **Regulatory Application**
   - For eligible products, the Legacy Safety Summary File (LSSF) may be accepted by notified bodies as evidence of conformity with Article 61 MDR in lieu of CEP and CER.

Justification:

Low-risk legacy devices in Classes I and I*, and certain non-active Class IIa devices, have been used safely in clinical practice for decades — often 20, 30, 50 years or more. These include a broad range of essential surgical and clinical tools such as scissors, forceps, clamps, chisels, retractors, hammers, tongs, tuning forks, probes, and other basic surgical and clinical tools (see Annex I). Many of these devices do not even involve direct wound contact (e.g. dressing scissors, kidney trays, surgical bowls, drape clamps, sterilization containers), yet are subject to the same extensive conformity assessment requirements as novel or high-risk products.

The current MDR obligations impose a disproportionate burden on these well-established technologies, particularly in cases where:

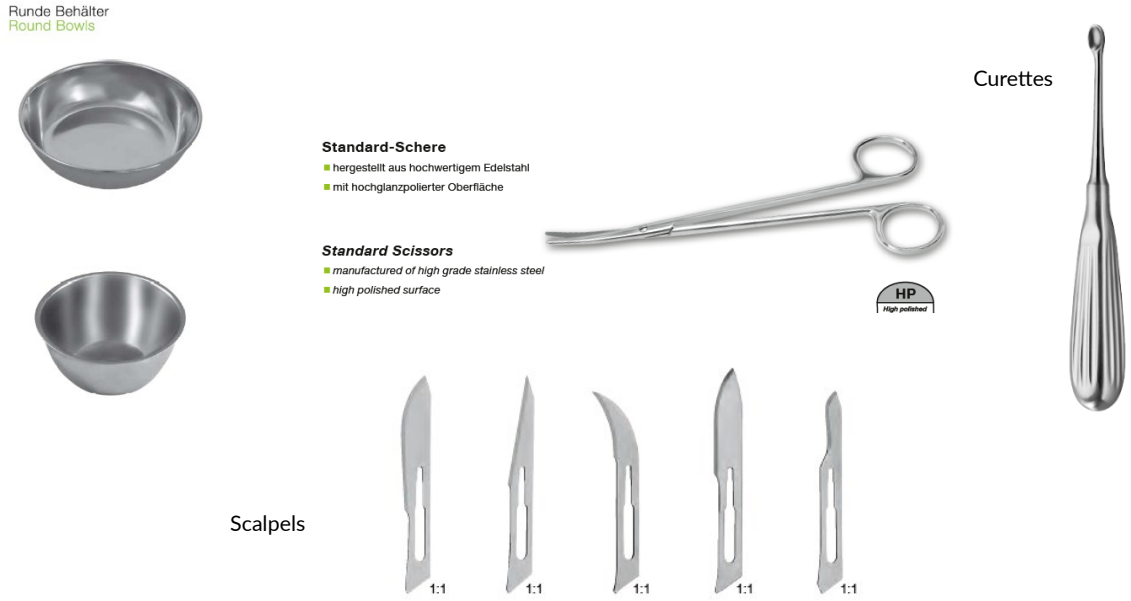
- no new clinical insights can reasonably be expected from further data generation (e.g. for a surgical scissor or cannula),
- there is no available scientific literature to support the clinical evaluation, and

- healthcare providers and professionals themselves have no academic interest and capacity to conduct and publish clinical studies on products which are considered generic in their mode of action, mature, safe, and indispensable in practice.

As explained in Chapter 3.1.1, the WET principle must be explicitly extended to include low and medium risk devices — including Class IIb non-implantables, Class IIa, Class Ir, Im, Is, and Class I devices. In these classes, the technical documentation requirements — particularly for clinical evaluation, usability studies, and repeated sampling — are frequently disproportionate and add no value to patient safety.

In practice, the requirement to produce a full Clinical Evaluation Report (CER) for such products consumes significant time and resources — with no tangible patient benefit or innovation. Worse, it leads to economically irrational decisions: Many low-risk devices are also low-cost items. When the regulatory compliance costs exceed the potential revenue, manufacturers discontinue these products. This trend is already visible in the EU market and threatens the continued availability of basic yet critical instruments.

Moreover, such products often have long service lives and are replaced only infrequently. As regulatory costs rise, the return on investment becomes unsustainable — particularly for SMEs. Without targeted regulatory relief, the MDR risks driving legacy products out of the market despite their well-documented safety and essential clinical function.



Notably, countries such as the USA, China, and Canada do not require full CERs for low-risk legacy devices and allow streamlined processes based on safe historical use.

Current MDR Proportionality Gap

While Article 61 and Annex XIV Part A (2) ("Depth and extent [of a clinical evaluation] shall be proportionate and appropriate to the nature, classification, intended purpose and risks of the device in question (…)") formally allow for a proportionate approach to clinical evaluation, the current practice falls far short of proportionality:

- Notified bodies demand extensive CERs even for low-risk devices — driven by stringent interpretations from authorities.

    - Notably, Class I products are equally affected by disproportionate documentation expectations. Although not subject to notified body assessment, the technical documentation requirements are almost identical to Class III products — creating an administrative burden without added safety benefit.
- This is despite no historical evidence of systemic risk under previous directives.

Further explanations:

Doctors use low-risk products across a wide range of clinical applications as tools for everyday use. Scissors for example have been in use for around 2000 years. They are made of stainless steel and belong to the fundamental tools of surgeons. There are no new scientific publications on scissors, sterilization containers, bowls, tuning forks, hammers, etc. (also see Annex I for more product examples). There is no interest given by healthcare professionals in collecting or publishing data on clinical safety, performance, and clinical benefit for those products.

Conclusion:

A robust combination of:

- MDR-compliant PMS,
- Risk management, and
- Established safety records

ensures high safety levels for low-risk devices and therefore protects patient safety. Full CERs are unnecessary in this context. Freeing manufacturers from these disproportionate requirements will allow them to:

- Maintain access to essential low-risk products, and
- Redirect resources toward clinical evaluation of higher-risk, innovative devices, where rigorous evaluation is more impactful.

This targeted approach will reduce unnecessary efforts and complexity without compromising patient safety. Moreover, this approach better aligns with international regulatory benchmarks (e.g. FDA 510(k), NMPA Art. 34).

3.1.3 NO ADDITIONAL CLINICAL DATA FOR CLASS I/IIA DEVICES THAT FULFIL PRODUCT-SPECIFIC ISO STANDARDS

Proposal/Amendment:

When a standardized Class I/IIa device fully meets the applicable product-specific ISO standards, and the manufacturer provides:

- Risk management documentation
- Biocompatibility data
- Manufacturing process verification and if applicable validation
- Cleanliness validation

this should be accepted as fully sufficient to demonstrate conformity with the GSPRs — without requiring additional clinical data or indication-specific benefit-risk analyses.

Justification:

For many established Class I/IIa medical devices — such as catheters, cannulas, surgical instruments, and endoscopic tools without pharmacological or metabolic effects — the state of the art is governed by long-standing, internationally recognized product-specific ISO standards. These standards already cover key safety and performance aspects, including:

- Mechanical, physical, chemical, and biological safety

- Usability and technical performance
- Compatibility with other devices
- Manufacturing process validation and cleanliness

According to the MDR, recognized harmonized standards can serve as a presumption of conformity with the GSPRs. However, in current practice, Notified Bodies often require additional clinical data and detailed benefit-risk analyses for these products — despite decades of safe market experience and despite the fact that such data provides no meaningful additional safety information for highly standardized products.

This leads to:

- Bureaucratic duplication of already covered requirements.
- Disproportionate regulatory costs and delays.
- Market withdrawal of essential products due to untenable compliance burdens.
- Resulting risks to supply security, especially for niche and high-volume standard products.

For these products, clinical outcomes are not primarily determined by the product itself, but by how the healthcare professional uses the device in a procedure.

- The physician selects the instrument based on clinical judgment — not based on manufacturer-provided clinical data.
- Adding clinical study requirements does not enhance patient safety, but diverts resources, delays market access, and threatens the availability of standard products.

Conclusion:

To restore proportionality and ensure that Europe maintains a stable supply of essential, standardized Class I/IIa devices, the MDR should:

- explicitly recognize norm-based conformity as sufficient for these products.
- clarify that no additional clinical data is required when the GSPRs are demonstrably met through standards and technical documentation.

This will maintain high safety standards, reduce unnecessary bureaucracy, and safeguard patient access to widely used and clinically indispensable devices.

Notably, Class I products are equally affected by disproportionate documentation expectations. Although not subject to notified body assessment, the technical documentation requirements are almost identical to Class III products — creating an administrative burden without added safety benefit.

3.1.4 Scope of Article 61(10)

Proposal/Amendment:

Article 61(10) MDR must be clarified, and exemption rules must be defined to provide a robust, criteria-based exemption framework for all medical devices where clinical data generation is unnecessary, redundant, technically or ethically questionable. This includes a revised legal wording and a formal recognition of validated non-clinical evidence pathways as equally sufficient in demonstrating conformity with the General Safety and Performance Requirements (GSPR).

Exemptions from clinical evidence requirements in the clinical evaluation process should generally apply when:

1. **Indirect Clinical Benefit**
   The device provides only indirect clinical benefit, enabling but not determining clinical outcomes. Ethically justifiable clinical research designs would not be scientifically suited to draw causality

conclusions or quantify clinical safety, performance or benefit on the basis of observable clinical endpoints (see also chapter 2.1)

2. **Compliance with general safety and performance requirements (GSPR) is demonstrated through validated non-clinical evidence such as:**
   - Biocompatibility testing
   - Mechanical and performance testing
   - Reprocessing validation
   - Usability/simulation testing
   - Risk management aligned with ISO 14971

3. **Legacy data acceptance**
   The device has accumulated robust post-market evidence (e.g. PMS, complaints, CAPAs) or long-standing market use confirms valid evidence of safety and utility, even without published clinical data.

4. **“Standard of care” or “Well-Established Technology (WET)” Status**
   The device meets the new formerly recognized WET criteria as proposed in Chapter 3.1.1, (also for Classes I, IIa, IIb) with standardized, mature designs and long histories of safe market use.

If any of this condition is given, clinical data requirements should be fully waived, as further data would not generate meaningful additional clinical insights. Furthermore, clinical research designs would result in unethical burden to patients, and due to resource constraints, the burden of further data generation may negatively impact the legal obligation of providing care to patients of health care providers.

If any justification is still considered necessary—explicit equivalence data should be accepted as sufficient. This avoids ethically questionable and scientifically redundant studies for devices whose clinical performance adds no new insights.

We propose a rewording to Article 61(10):

> „Without prejudice to paragraph 4, where the demonstration of conformity with the general safety and performance requirements based on clinical data is not deemed scientifically or ethically appropriate, is not feasible with appropriate effort (e.g. due to lack of interest or insufficient response and support from health care providers), or where additional clinical evidence would not lead to new relevant information regarding safety, performance or benefit, the manufacturer shall provide adequate justification for any such exception.
>
> This justification shall be based on the results of the manufacturer’s risk management and take into account:
>
> - the nature and risk classification of the device,
> - the specifics of the interaction between the device and the human body,
> - the intended clinical function (direct or indirect),
> - and the manufacturer's claims.
>
> In such cases, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II that conformity with the general safety and performance requirements is demonstrated through non-clinical testing methods alone, such as:
>
> - performance evaluation,
> - bench testing,
> - simulation and usability testing,

- animal or cadaveric studies,
- pre-clinical evaluation,
- and, where appropriate, legacy data from equivalent devices.

Non-clinical evidence shall be deemed sufficient, where:

- the device enables but does not determine clinical outcomes (indirect clinical benefit and expectable non-quantitative causal relationship),
- clinical endpoints cannot reasonably or ethically be defined,
- or where the product's safety and performance can be validated through standardized test methods in line with the state of the art.

The Commission shall adopt implementing acts or guidance documents to define criteria for such devices, including well-established technologies, products with indirect clinical benefit, and relevant risk thresholds."

Such a clarification would align the MDR with international best practices and ensure proportionality for devices where the clinical value of additional data generation is negligible. For example, under China's NMPA regulation (Article 34), certain well-characterised and long-marketed devices can be exempted from clinical evaluation if their function, design, and safety profile are well-established. Such models could serve as inspiration for the EU to define clearer and more practicable exemption rules under Article 61(10).

Justification:

Although Article 61(10) theoretically allows the use of non-clinical evidence, it remains inapplicable in practice, with Notified Bodies rejecting justifications due to the lack of concrete guidance or explicit recognition in the law. Article 61 (10) MDR is furthermore creating uncertainty on its interpretation and correct application, especially for medical devices falling into the low to moderate risk class (Class IIa) and in the moderate to high (class IIb) risk class, where the requirement to perform a clinical investigation for the demonstration of conformity with the GSPR is not imposed by the legislation. It is important that this option, which is already outlined in the legal text, is applied, and made functional.

Modern technologies now offer a range of scientifically valid non-clinical methodologies, including:

- Digital twins
- Simulation and modeling
- Curated databases and retrospective patient data
- In silico studies and physical/digital phantoms

The decisive factor should not be the source of the data (clinical vs. non-clinical), but the scientific validity and relevance of the methodology whether the data can be extrapolated to the expected clinical use of the device and in the intended clinical use environment, and whether the non-clinical data solely is sufficient to cover all clinically relevant characteristics and claims made on the device by the manufacturer, and thus demonstrate the conformity of the device with the applicable GSPR.

Conclusion:

A clarified and operationalized Article 61(10) is essential for restoring proportionality and legal reliability in the MDR. Devices that are well understood, standardized, and long proven should not be subject to additional clinical data demands. For many well-established technologies, the generation of new clinical data is scientifically unfeasible and offers no additional insights and may even raise ethical concerns. By allowing criteria-based exemption pathways (see chapter 3.1.1), supported by risk management, simulation, usability, and real-world legacy data, the MDR can better balance safety with innovation, SME competitiveness, and patient access. Integration of such a framework into MDR 2.0 would reflect global regulatory convergence and scientific pragmatism.

3.2 PROPORTIONAL SAMPLING REQUIREMENTS

Proposal/Amendment:

We propose to align sampling practices with proportionality and risk:

1. Amend Article 52(4) and (6) MDR and Annex IX, and revise MDCG 2019-13 (Rev.1) to allow for the following adjustments:
    - Full exemption of Class IIa devices from routine sampling; sampling only on a trigger-based or justified basis during surveillance audits.
        - Following the proposed expansion of the well-established technologies concept to additional risk classes (see chapter 3.1.1), the classification of a device as a WET should systematically lead to exemptions from routine sampling obligations. One representative sample per generic device group during pre-market conformity assessment for Class IIb devices.
    - Smart, risk-based sampling for Class IIb devices during surveillance:
        - Removal of the rigid "one Technical Documentation (TD) per year" requirement for small or low-risk portfolios,
        - Recognition and reuse of previously assessed TDs across certification cycles and product families: The consistent application of this principle should be reinforced to avoid duplicative reviews of essentially identical documentation, strengthen legal certainty, and reduce unnecessary administrative burden.
        - Exemptions from repeated sampling of identical or highly similar devices based on risk and similarity.

Recognize and protect SMEs and companies with small product portfolios by ensuring a level playing field through proportionate review obligations and sampling policies adapted to portfolio size, risk classification, and technological maturity.

Justification:

<u>From Risk-Based Strategy to Rigid Routine</u>

Sampling—the selective assessment of TD—is a core part of the conformity assessment procedure under Article 52(4–6) and Annex IX of the MDR. The regulation allows notified bodies to use representative samples, taking into account technological novelty, design similarity, manufacturing processes, and previously assessed devices. The MDR leaves intentional flexibility, encouraging a proportionate and risk-based approach.

Unfortunately, this principle has been undermined by MDCG 2019-13 Rev. 1 (Dec. 2024), which sets rigid quotas:

- It is expected that 15% of devices from each category and from each generic device group covered in the certificate will be sampled during its validity – taking into account the maximum validity of 5 years (5% in exceptional cases).
- At least one TD must be assessed per year—regardless of portfolio size or previous assessments.

Furthermore, the guideline is unclear regarding the continuation of a sampling plan during recertification. Often, the plan is reset by the notified bodies during recertification without considering audits from the previous period. In a consequence, the approach leads to inefficient repetition, particularly for manufacturers with small, standardized portfolios—often SMEs. Devices that have not changed technically must be resubmitted, wasting time and resources without yielding any safety-relevant insights.

Class IIa – Well Understood, Overregulated

Class IIa products typically carry moderate risk and are well standardized. Many are produced by SMEs using established designs. Yet they face disproportionate sampling burdens:

- Annual assessments of Basic UDIs with identical design,
- Redundant reviews of unchanged TDs across consecutive years,
- Requests for additional documentation despite no product modifications.

This leads to:

- Resource drain on regulatory departments,
- Delay or cancellation of innovation projects,
- Postponement of investments in new technologies.

The current system undermines the regulatory objective of proportionality—penalizing those who operate with established, safe devices.

Class IIb – Oversight, Not Overload

For Class IIb devices, rigorous pre-market evaluation remains essential. However, during the post-market phase, intelligent, data-driven sampling is more appropriate. In many cases, one representative device per generic product group provides sufficient insight to safeguard regulatory compliance.

- Legal Inconsistencies and Bureaucratic Overreach

The current interpretation contradicts the legal foundation of the MDR. Article 52(4–6) and Annex IX only require representative sampling—not annual quotas or repeated tests.

The shift from a flexible to a rigid model—based on non-binding MDCG guidance—has created legal uncertainty and administrative overload. Notified bodies, lacking legal clarity, often adopt defensive strategies that further escalate documentation demands.

Conclusion:

The MDR was introduced to enhance patient safety—not to block innovation or overburden SMEs with redundant compliance tasks. A risk-based, proportionate sampling practice is not only urgently necessary—it is already legally permissible. We call for a return to regulatory principles that balance safety with efficiency, proportionality, and trust in the manufacturer's demonstrated conformity.

3.3 Reducing bureaucracy in reporting and documentation

3.3.1 Abolition of Article 10a MDR or replacement through new platform approach

Proposal/Amendment:

The current obligation under Article 10a to notify an interruption or discontinuation of supply should, in principle, be repealed altogether. The provision has proven to be ineffective, non-operational, and adds administrative burden without tangible benefit for patients or regulators.

However, should a full repeal not be politically or procedurally feasible in the short term, we propose the following targeted amendments as transitional improvements.

First, instead of requiring a notice period of at least six months in advance and using the vague term "reasonably foreseeable," the provision should state:

"The notification shall be made by the manufacturer as soon as it is determined that an interruption or discontinuation of supply can no longer be avoided."

Second, a central EU-wide Critical Medical Device List should be established, inspired by the U.S. FDA model. Devices and product categories included on this list would be automatically classified as critical and could be exempt from the notification requirements under Article 10a.

Most importantly, to make any notification mechanism truly valuable, we propose the creation of a central EU-wide online platform, where healthcare professionals and institutions can directly report missing or discontinued devices. Such a real-time reporting platform would ensure that the needs of users and patients come before bureaucracy and would make the system fit for the realities of healthcare delivery.

Unlike the current passive and non-responsive structure of Article 10a, a platform approach would enable bidirectional communication and support real-world use cases such as:

- demand aggregation across Member States,
- automatic alerting mechanisms to relevant authorities and manufacturers,
- data-based prioritisation of regulatory interventions (e.g. accelerated grandfathering, temporary approvals).

This approach would close the information gap between users, industry, and regulators, allow early identification of emerging care gaps, and establish a data-driven basis for timely and targeted regulatory responses. In the medium term, the platform model should be seen as the preferred structural alternative to the current Article 10a framework.

Justification:

Article 10a MDR, introduced to allow for exceptional authorisation of critical devices, has proven ineffective as it is reactive rather than preventive. The reporting mechanisms are fragmented, and so-called escalation pathways lack purpose in the current legal framework — there is no defined regulatory action that can be triggered in response to a 10a notification. Furthermore, notification depends on recognizing a supply gap that may already have harmed patient care, especially in the case of niche or low-volume products. While it is contested whether the non-availability of a specific medical device alone constitutes harm – given that manufacturers only guarantee device safety, not therapeutic success – this debate must not distract from the real-world impact on clinical workflows and patient outcomes in cases where no alternatives are available.

Under the current Article 10a MDR, manufacturers are expected to demonstrate that the interruption or discontinuation of a device would result in “serious harm or risk of serious harm to patients or public health” in one or more Member States. In reality, this is not feasible to deliver. Manufacturers do not have full market visibility, such as access to data on competitors' product availability or distribution capacities. As a result, accurate criticality assessments are often not possible.

Furthermore, the requirement to notify at least six months in advance is unrealistic in practice. Critical decisions – e.g. due to supply chain failures or sudden economic unviability – in vast majority emerge on short notice. The current phrasing “reasonably foreseeable” offers too much interpretive ambiguity and no legal certainty.

While Article 10a is designed as a preventive tool requiring notification prior to market effects, it remains a one-way mechanism without reactive capacity. Authorities neither have the mandate nor the operational framework to respond meaningfully to these early alerts.

In its present form, Article 10a fails to achieve its intended effect. It neither ensures continuity of supply nor provides a usable framework for authorities. On the contrary, it imposes disproportionate bureaucratic burden without measurable benefit to patients.

Conclusion:

Article 10a MDR, in its current state, is not fit for purpose. It lacks practical applicability, creates unnecessary administrative overhead, and does not effectively protect patient access to essential devices. The absence of actionable follow-up also undermines the very logic of escalation procedures under Article 10a.

3.3.2 Reduced PSUR obligations (art. 86)

Proposal/Amendment:

Article 86 is amended to reduce Periodic Safety Update Reports (PSUR) obligations to class III and IIb implantables only.

Furthermore, Article 86 is amended to introduce risk-based intervals and trigger-based review logic:

- After the first four years of PMS implementation with current PSUR intervals (as per Article 86 MDR), the reporting frequency shall be reduced to:
    - Every two years for Class III and Class IIb devices,
    - Every four years for Class IIa devices (if no safety-relevant developments occur),
    - No recurring PSUR requirement for Class I devices — instead, a simplified PMS report according to Article 85, updated and reviewed only when clinically justified.

This adjustment is proposed within a broader, consistent system of regulatory relief, which includes exemptions from re-certification, reduced sampling obligations, and targeted QMS audits — all linked by a risk-based-approach.

Justification:

The current requirements under Article 86 MDR/Article 81 IVDR demand periodic updates (annually for Class IIb/III, biennially for Class IIa) regardless of product maturity, market experience, or actual risk signals. This applies equally to new and legacy products. This static model leads to substantial administrative effort for both manufacturers and Notified Bodies, particularly for legacy, low risk products and well-established products with stable safety records. It does no align resources with actual patient risk.

We propose a coherent regulatory framework in which PSUR, certification renewal, sampling, and surveillance audits are subject to triggered review mechanisms across the full quality management system (QMS) spectrum. These should apply according to triggers:

- There is a substantiated change in the state of the art, such as new clinical standards or significant technical advances. (e.g. major clinical paradigm shift or new guidance affecting product safety or performance),
- Significant market measures (e.g. recalls, FSCA) or confirmed trends indicate increased risk.
- The intended use or indications of the device are expanded.

Single vigilance reports or isolated incidents, by contrast, should not automatically trigger re-certification or PSUR reviews. Regulatory action should be based on trend data or broader corrective measures — not isolated events.

Likewise, the repeated reassessment of identical documentation (e.g. CERs, PMS Plans) should be avoided unless new risk arises. This applies equally to PSURs, PMS Reports (Class I), technical documentation, and clinical evaluations. Documentation that has been reviewed once should not be reviewed again unless truly necessary. This logic must be extended to Class I devices, which are currently often subjected to redundant PMS documentation and reviews. A proportional, simplified PMS report (per Article 85 MDR) — to be updated and reviewed only when justified — would restore balance and free up resources for genuinely risk-relevant oversight.

The continued requirement to update and reassess PSURs annually — even where no new insights are expected — diverts resources from genuine risk surveillance. For example, a stainless-steel surgical scissor that has been in use for over 100 years does not suddenly become non-compliant only because a new version of ISO 10993 is released. It is not reasonable to assume, that scissors with 100 years market history suddenly become non-biocompatible.

In such cases, automatic certificate prolongation or document exemptions should apply.

Our important message in this context: We acknowledge, that post-market surveillance (PMS) is a very important tool of the MDR legislation for the continuous and ongoing risk monitoring of medical devices.

With the proposed amendment, all medical devices – also new products - are closely monitored after the initial product certification and the implementation of the PMS plan with the Periodic Safety Update Reports (PSUR) at intervals according to Art. 86 MDR in the first four years. After such an initial marketing phase, the medical devices can be assessed as proven safe and effective if no reports of vigilance cases or significant trend changes occur during this period.

PSUR reports will then only be required every two years for medical devices in class IIb and III, (or every four years for risk class IIa if no PSUR reduction may take place for this risk class). If there are vigilance cases, the previous frequency (according to Art. 86) of one (or two) years remains in place and would have to be observed again for the next four years following a report.

For legacy devices, this would mean that they would mostly fall under the extended interval regulation if they had already been on the market for four years prior to certification under MDR and thus differ from new product certifications.

The fact that the contents of the reports sometimes change only marginally, if at all, should also be taken into account. Notified bodies are reading and proving the same information again and again.

Conclusion:

The proposed change will relieve the notified bodies of the annual review of the PSUR reports for product classes IIb and III and streamline class IIa PSUR reviews completely and thus lead to a cost reduction due to less work for the Notified Bodies and manufacturers, without any loss in product safety.

We assume that demanding an exemption from re-certification (as described in former position paper[9]), reduced sampling, and a simplified PSUR all at once may raise consistency concerns.

The fact is: The proposed PSUR interval adjustments are essential but must be integrated into a logically consistent system interlinked with the broader QMS surveillance. This system should align:

- reduced PSUR frequency,
- exemptions from re-certification,
- proportional sampling, and
- audit requirements under one risk- and event-based framework.

We propose introducing a risk-based framework of event-triggered or need-based re-certifications and reviews — e.g. based on changes to state-of-the-art standards. To this end, clear and objective criteria should define what constitutes a relevant change. A 100-year-old stainless-steel surgical scissor does not become non-biocompatible just because ISO 10993 was updated.

The decision to re-certify or revise PSURs should not be triggered by single vigilance events alone. Instead, broader market measures or corrective actions should be considered a more appropriate trigger.

[9] MedicalMountains suggestions MDR 202407_EN.pdf from July 2024

The same logic should be extended to Class I devices and their PMS Reports. Redundant reviews should be avoided; documentation should only be created once — and reviewed once — if it genuinely contributes to patient safety.

Such an approach ensures effective, targeted oversight — focused on actual risk rather than regulatory repetition. It strengthens patient safety by enabling Notified Bodies and manufacturers to concentrate on relevant developments, while reducing avoidable workload and cost, especially for SMEs.

3.3.3 AVOIDANCE OF MANDATORY DOUBLE VIGILANCE REPORTING TO NOTIFIED BODIES

Proposal/Amendment:

Remove the expectation or informal obligation to submit vigilance reports to Notified Bodies. Limit vigilance reporting exclusively to competent authorities, as originally intended under the MDR.

Justification:

Under the current interpretation of the MDR, manufacturers are expected to share vigilance reports—including serious incident reports and Field Safety Corrective Actions (FSCA) — with their Notified Bodies, in addition to submitting them to the competent authorities. Articles 87–92 MDR govern vigilance activities and define Member States' authorities as the recipients of incident reports and trend analyses—not Notified Bodies.

But although this is not explicitly required in the legal text of the MDR it has become a quasi-obligation through the expectations raised during audits and conformity assessments. The fact is, that Notified Bodies do not have legal authority to act on vigilance data (e.g., they cannot initiate market surveillance or sanctions). The evaluation of trends, signal detection, and regulatory actions must be carried out by competent authorities, such as BfArM in Germany or ANSM in France. Nonetheless, notified bodies spend time reviewing the reports and charge high fees to legal manufacturers for work that is already being done by others.

Sharing vigilance reports with NBs leads to unnecessary duplication and system overload of effort with no benefit. Resources are spent on processing, storing, and discussing reports that NBs are not mandated to act upon. This increases the audit burden without improving patient safety or regulatory efficiency.

For NB, practical demonstration that the company is carrying out vigilance is sufficient. This is made during conformity assessments, where manufacturers can demonstrate vigilance competence through a walk-through of a representative vigilance case, the description of the internal SOPs and decision-making processes. This is sufficient for the NB to assess conformity with the MDR without needing every report.

Conclusion:

Eliminating the expectation of NB reporting will reduce significant costs at notified body side and consequently for medical device manufacturers. It will also allow Notified Bodies to focus their limited resources on risk-relevant assessments and relieve unnecessary administrative burden on the industry. Clarification is both practical and necessary to align regulatory practice with the legal text.

3.3.4 STREAMLINING TREND REPORTING REQUIREMENTS

Proposal/Amendment:

A trend report represents a duplication of existing mechanisms and is bureaucratic in its current form. Revise Article 88 MDR and associated implementing guidance to either eliminate or significantly simplify the obligation for separate trend reporting in cases where existing PMS and CAPA mechanisms are already deemed sufficient and systematically audited.

Justification:

Trend reporting has originally been understood by legal manufacturers as a straightforward tool to inform authorities about observable trends in product performance or safety in an uncomplicated manner. In practice, however, the implementation has become an unclear administrative requirement.

Relevant articles in MDR:

- Article 88 MDR – Trend reporting: requires manufacturers to report "any statistically significant increase in the frequency or severity of non-serious incidents or of expected undesirable side-effects."
- Annex III MDR – Technical Documentation on PMS: requires manufacturers to collect and evaluate data on product performance and safety in a systematic way.
- Article 83 MDR – Post-market surveillance system: defines the general PMS framework.
- Article 85 MDR – PMS report: requires manufacturers of class I devices to prepare regular PMS reports.
- Article 86 MDR – Periodic safety update report (PSUR): required for Class IIa, IIb, and III devices.
- CAPA (Corrective and Preventive Action) procedures – evaluated during notified body audits, are already in place to address recurring issues effectively.

Notified bodies already audit statistical methods and the systematic procedure for recording any information on the product (PMS plan, Annex III MDR) during annual surveillance audits, particularly in connection with customer complaints and other feedback from the market (PMS), which is also the subject of Article 88 in the broadest sense. And as part of the CAPA audit and the reports in accordance with Art. 85 and 86 MDR, it is checked how and when the manufacturer plans and implements corrective and preventive actions and verifies the effectiveness of the measures taken. These mechanisms are robust and sufficient to identify patterns of serious incidents or performance issues at an early stage, being able to take countermeasures immediately.

The fact is: A manufacturer will take any complaints seriously and not wait until a trend that will be proven by statistical means occurs.

Moreover, the notion of a “trend” as defined in Article 88 is practically unworkable in many cases:

- Statistical significance often requires a large data set—something that many niche products or low-volume devices do not generate.
- In reality, even a small number of similar complaints will trigger internal actions under PMS/CAPA without waiting for statistical thresholds to be met.
- There is also no clear threshold or guidance on when to interpret observations as “statistically significant increases,” which results in inconsistent implementation and legal uncertainty.

Conclusion:

The current trend reporting obligation under Article 88 MDR creates redundant bureaucracy without adding measurable value to patient safety - especially when robust PMS, PSUR, and CAPA processes are already in place. Moreover, for rarely used or low-volume devices, the trend reporting obligation is often not feasible, while still being formally required. We recommend a targeted amendment to Article 88 MDR that:

- Limits trend reporting to cases where data quantity and statistical validity are assured,
- Allows reliance on existing PMS/PSUR mechanisms for signal detection, and
- Provides clear thresholds and practical criteria to distinguish a “trend” from isolated events.

This would reduce unnecessary administrative burden and legal uncertainty—particularly for SMEs—while maintaining high safety standards.

3.3.5 STREAMLINING CONTENT AND ACTUALIZATION FREQUENCY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) REQUIREMENTS

Proposal/Amendment:

The current SSCP process under the MDR is disproportionate, duplicative, and inefficient — particularly for well-established technologies and standardized devices that are already subject to extensive regulatory controls. We call for a risk-based, streamlined SSCP approach.

Specific proposals:

1. Trigger-based SSCP updating via Common Specification (CS):
    - Develop a Common Specification under Article 9(1) MDR to amend Annex XIV Part B.
    - Introduce Key Risk Indicators (KRIs) within PMCF processes, triggering updates to the SSCP only when clinically relevant new information is identified.
2. Exempt WET from annual SSCP updates:
    - Amend article 61(11) MDR to:
        - Exempt WET from the obligation of annual SSCP validation, unless KRIs indicate relevant changes.
        - Clarify that information already present in the IFU, implant card, or labelling need not be redundantly repeated in the SSCP.
          → Allow full or partial integration of SSCP content into the IFU where appropriate.
3. Reform SSCP upload and validation process:
    - Amend article 32 MDR to:
        - Permit direct manufacturer upload of SSCPs to Eudamed with subsequent validation or approval by the Notified Body (NB) if required.
        - Ensure that SSCP updates do not trigger additional NB fees unless material changes are being made.
        - Stop continuous validation and revalidation: reviews should be part of existing audit/sampling cycles.
4. Simplify SSCP content (MDCG 2019-9):
    - Remove content that is not directly relevant to professional users or patients.
    - Clarify that references to harmonized standards are not needed in the SSCP.
5. Restrict the language requirements for SSCPs to:
    - English for EU-level submissions and professional users.

Justification:

In general, the SSCP under Article 32 and Annex XIV of the MDR is intended to enhance transparency for high-risk and implantable devices and to ensure that critical safety and performance information is available to patients and healthcare professionals. However, its current implementation under Article 32 MDR and MDCG 2019-9 is disproportionate, duplicative, and inefficient. Key issues include:

1. Redundant documentation burden:
    - Significant duplication of information already required under other parts of the MDR like IFU, implant card, and patient information leaflet (e.g. intended purpose, performance characteristics, safety information, risks, clinical benefits) leading to inefficiencies.

- For example, manufacturers of implantable devices must provide an implant card and a patient information leaflet that includes the intended purpose, risks, expected lifetime, and follow-up advice. The SSCP is required to provide nearly identical content for patients (e.g., intended purpose, risks, follow-up). This creates unnecessary redundancy, particularly for implantables.
- For WET medical devices (e.g., staples, sutures, meshes), periodic updates to the SSCP will not reveal new developments relevant to health care professionals (HCPs) and patients but are redundant exercise, imposing bureaucratic and financial burdens (€3,000–6,000 per update). Consider: WET are exempted from implant cards (Article 18(3)) and full technical documentation assessment (Article 52(4)).

2. Misaligned validation process:
   - The requirement forces manufacturers to produce and validate an SSCP for a device that does not (or no longer) change in any material sense.
   - Current processes lead to inefficient sequencing. In practice, SSCP validation often occurs before the clinical evaluation is finalized leading to discrepancies and subsequent corrections—highlighting a lack of process reliability.
   - PSUR-based SSCP updates are subject to full NB revalidation even for minor or editorial changes, such as updated standards, reference literature, or negligible shifts in incidence rates.
   - Inconsistent Notified Body interpretations further increase uncertainty.
3. Eudamed upload restrictions:
   - Current rules force NB-controlled uploads. It forces manufacturers to either translate pre-emptively into all possible languages or face additional fees per Member State and version. It further creates financial and logistical pressure, especially for SMEs, as the manufacturer cannot independently ensure timely publication, delaying publication.
4. Limited benefit for patients and professional users:
   - SSCPs are predominantly used by professional users and regulators, not by the general patient population making extensive “patient-friendly” translations across all EU languages disproportionate. The highly technical language makes them inaccessible to laypersons despite being translated.
   - Professional users benefit from other concise, targeted information — not a duplicated regulatory document like the SSCP.
   - Existing guidance (e.g., MDCG 2019-9) acknowledges the complexity of the SSCP and its professional focus.
   - In practice, many manufacturers integrate the patient-relevant SSCP content into a single document, avoiding duplication with implant cards or separate patient information leaflets — an approach supported by existing MDCG guidance.
   - Updating the SSCP regularly by minor changes not of relevance for safety and efficacy has no additional benefit for patients and professional users. References to harmonized standards are without any benefit for professional users. It is the obligation of the manufacturer and part of audit and sampling by the notified body to ensure, that harmonized standards are taken into consideration for a product (SOTA)

Conclusion:

The current SSCP system, while well-intentioned, has degenerated into an administrative exercise with questionable added value — especially in cases where no substantive product changes occur and especially for WET implantables, which are already exempt from other documentation requirements under Articles 18(3) and 52(4) MDR.

We therefore call for an immediate move to a risk-based SSCP regime:

- Trigger-based updating aligned to KRIs in PMCF
- Exemption of WET from unnecessary annual updates unless justified
- Direct manufacturer upload in Eudamed with streamlined NB oversight
- Simplified, targeted content focused on genuine user needs.
- Reduced language requirements, aligned with actual patient and professional user outreach.

Such reform maintains transparency and safety while reducing unnecessary costs, duplication, and workload, particularly for high-volume, low risk implantables and established product lines. It would significantly improve proportionality, predictability, and efficiency—without compromising the intended benefits of the SSCP.

3.3.6 DISPENSABLE LANGUAGE REQUIREMENTS FOR PROFESSIONAL USE

Proposal/Amendment:

Article 10(11) of Regulation (EU) 2017/745 is amended as follows:

> "Manufacturers shall ensure that the device is accompanied by the information set out in Sections 23.1 to 23.4 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient."

The following paragraph is added:

> "However, for devices intended solely for professional use within healthcare institutions or by healthcare professionals, the instructions for use and user interfaces may be provided only in English.
> This derogation shall not apply to devices intended for lay users or home use, which shall continue to comply with national language requirements."

Justification:

Currently, manufacturers face a fragmented landscape of language obligations:
In approximately half of EU member states, instructions for professional users may be provided in English. The other half require national language versions, even if the product is not used by laypersons. This inconsistency results in significant additional effort and cost for companies who must translate IFUs and user interfaces into multiple rarely used languages, often for markets with minimal demand. In some cases, this has led to the withdrawal of products from individual EU countries, reducing availability for patients and clinicians.

In addition, there is a systemic problem with ensuring the accuracy of translations: Neither manufacturers nor Notified Bodies typically have the linguistic expertise to verify all EU languages. Even certified translation agencies frequently produce inadequate translations due to a lack of understanding of the specific medical and technical vocabulary used in the field of medical devices. This forces manufacturers to rely blindly on third-party translation providers — a setup that paradoxically increases, rather than mitigates, the risk of misinterpretation and patient harm. This regulatory approach thus introduces a safety concern where none existed before.

Conclusion:

A harmonized language model (EN) for professional-only use would:

- Simplify documentation workflows and reduce translation costs.
- Eliminate regulatory uncertainty and national deviation.
- Maintain safety for trained healthcare professionals.
- Support EU-wide initiatives for bureaucracy reduction.
- Avoid translation-related safety risks due to inaccurate or misunderstood instructions.

This measure would not apply to layperson-facing devices or patient use, for which national language requirements would remain in full effect.

3.4 REGULATORY ENABLERS FOR ORPHAN DEVICES[10] IN EUROPE

Proposal/Amendment:

We propose a targeted 'Grandfathering' and 'Recognition' pathway for orphan devices.

1. **Grandfathering of orphan devices**

A new Article 120a is inserted into the MDR to permit the grandfathering of orphan medical devices with a long-standing, safe clinical history in order to ensure their continued supply.

This pathway should apply to:

- Orphan legacy devices (CE-marked under MDD, article 120 MDR) with demonstrably safe use over many years (based on PMS, complaint data, market experience, records of historic safe use etc.),
- Orphan devices withdrawn from the market between 2017 and 2021 due to MDR burdens, but for which there is still clinical demand.

2. **Conditional market access based on foreign regulatory approval**

Adopt a mechanism—similar to the Swiss model—to allow conditional market access or national derogations for orphan devices already approved by other trusted regulatory systems, such as the U.S. FDA.

Such a mechanism could include the following key elements:

- Recognition of FDA-approved devices (PMA or 510(k)) or equivalent approvals from jurisdictions with comparable safety and effectiveness standards.
- A simplified notification procedure to EU competent authorities replacing full conformity assessment.
- Manufacturers obligations to:
    a. justify the medical relevance and added value of the device in the EU (e.g. unmet medical need, innovation benefit),
    b. implement EU-based post-market surveillance and incident reporting, and
    c. ensure proper risk classification alignment and compliance with EU-specific labelling requirements.

While the focus of this proposal lies on orphan and niche medical devices, the underlying concept warrants broader consideration and could serve as a blueprint for broader regulatory relief, helping to safeguard supply continuity and promote innovation while maintaining patient safety.

[10] According to MDCG Guideline 2024-10, a medical device or an accessory is considered an "orphan device" if it meets the following criteria:

1. Rare Disease Criterion: The device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that affects no more than 12,000 individuals in the European Union per year.
2. Additional Qualifying Criterion: At least one of the following conditions must also be met:
    - Lack of Alternatives: There is an insufficiency of available alternative options for the treatment, diagnosis, or prevention of the disease or condition.
    - Expected Clinical Benefit: The device offers an option that provides an expected clinical benefit compared to available alternatives or the current state of the art for the treatment, diagnosis, or prevention of the disease or condition, considering both device- and patient population-specific factors.

3. **Voluntary mutual recognition agreement (MRA)**

Negotiate a Mutual Recognition Agreement (MRA) between the EU and the U.S. (and/or Switzerland, Canada, Japan, Australia) for orphan or niche-use medical devices, allowing:

- Mutual acceptance of conformity assessment results (notified body/FDA decisions).
- Streamlined registration and vigilance obligations.
- Defined scope: limited to orphan, paediatric, or specialty surgical devices.

This MRA could include:

- A device registry or EU notification portal.
- Alignment of PMS and vigilance obligations, with reliance on existing foreign systems where appropriate.
    - It should be clarified whether additional EU-specific requirements such as the Summary of Safety and Clinical Performance (SSCP) would still apply to devices placed on the market under the MRA. It would be disproportionate to require full EU-specific documentation like SSCPs in cases where no new clinical data were created.
- Joint EU–foreign authority review board to assess borderline cases.

In addition, to enable the success of any of these solutions, we propose replacing Article 10a with a more effective and streamlined approach: the creation of a central EU-wide online platform where healthcare professionals can directly report missing or discontinued devices — regardless of whether the product is classified as an orphan device (see explanation in chapter 3.3.1). This should be closely linked with the mandatory use of EUDAMED from January 2026 onwards, where manufacturers will also be required to enter the planned date of discontinuation for each device.

In parallel, it should be considered whether extensive use of national derogations (Article 59) by individual Member States — once they reach a certain threshold in volume — risks undermining the overall coherence and objectives of the MDR.

Justification:

A study conducted by MedTech Europe in 2024 showed that only 52% of medical device manufacturer respondents to the survey that produce orphan devices indicated they will transfer all their orphan devices to the MDR. However, 29% indicated they do not plan to transfer any of their current orphan devices to the MDR.[11]

Unlike the U.S. 510(k) system, which allows reference to predicate devices with proven safety and substantial equivalence, the EU has no mechanism to acknowledge the clinical value and safety history of pre-MDR/IVDR devices. Instead, all products—no matter how well-established—must go through a full, costly reassessment under the new regulations.

Even Article 10a MDR, introduced to allow for exceptional authorisation of critical devices, has proven ineffective as explained in chapter 3.3.1:

- Article 10a MDR, in its current state, is not fit for purpose. It lacks practical applicability, creates unnecessary administrative overhead, and does not effectively protect patient access to essential devices. The absence of actionable follow-up also undermines the very logic of escalation procedures under Article 10a.
- In practice, NCAs from different Member States approach manufacturers individually for additional details on each product concerned. This often requires first establishing GDPR-compliant data-sharing agreements and other legal formalities — creating significant administrative burden. This process ties up valuable resources on both sides (authorities and

[11] https://www.medtecheurope.org/wp-content/uploads/2025/01/mte-ivdr-mdr-survey-report-highlights-final.pdf

manufacturers) — resources which would be better invested in maintaining the availability of medical devices on the market.

There is no effective system today to detect or prevent the silent disappearance of valuable technologies.

The MDCG Guide 2024-10[12] on the clinical evaluation of medical devices for rare diseases now allows for restrictions on pre-market clinical data for orphan devices and provides guidance on the generation of post-market clinical data – both important measures to improve requirements. However, more far-reaching solutions that go beyond solving the problem of clinical evidence but reduce overall cost – which is the root cause for discontinuations - are needed to ensure the profitability of and thus the supply of orphan devices.

Further explanations:

On May 28, 1976, the Medical Device Amendments to the Food, Drug, and Cosmetic Act (FD&C Act) was passed in the USA. In this context, products that were already on the market before the FD&C Act came into force were classified as so-called preamendment devices (Section 513). A large proportion could be placed on the market according to the principle of so-called "grandfathering", provided that no significant changes were made.

When drafting the MDR, the pragmatic grandfathering approach would have been more than appropriate for all existing products with low and medium risk potential, because unlike in the USA in 1976, all existing products in the EU have already been subjected to a compliance assessment procedure in accordance with the MDD. It could therefore be assumed that there was a high level of protection potential for patients and users.

Conclusion:

To prevent further loss of vital technologies, the EU must establish a proactive and legally robust grandfathering framework for legacy and orphan devices—complemented by mechanisms for foreign recognition and real-time clinical feedback.

This new framework should:

- Accept historic conformity under MDD or FDA 510(k) as sufficient in justified cases,
- Include discontinued devices where foreseeable gaps in care exist,
- Enable fast-track reapproval where needed,
- Be clinically sensible, legally feasible, and humanely responsible.

Ultimately, this is not just a regulatory question—it is a matter of medical necessity. It cannot be the intention of EU legislators that patients are denied life-saving interventions simply because a proven, safe product is no longer economically viable under the current system.

3.4.1 SUPPLEMENT FOR REFLECTION: BROADER APPLICATION OF ARTICLE 120A GRANDFATHERING?

While our proposal of grandfathering focuses on orphan devices, the rationale for introducing an article 120a MDR should be discussed to maybe not be restricted to orphan products alone. The structural flaws identified — such as disproportionate evidence requirements and lack of differentiated pathways — apply equally to a wide range of general medical devices, including those in high-volume use. The underlying arguments — the recognition of long-standing clinical use and proven safety — are equally valid for all legacy devices that were discontinued prior to MDR

[12] https://health.ec.europa.eu/document/download/daa1fc59-9d2c-4e82-878e-d6fdf12ecd1a_en?filename=mdcg_2024-10_en.pdf

application, particularly between 2017 and 2021, due to regulatory uncertainty or transitional market pressures. In practice, many non-orphan devices with a strong clinical track record were withdrawn simply because, at the time, the regulatory framework (especially regarding clinical evaluation) was not sufficiently clarified — for example, prior to the publication of key MDCG guidance documents. In certain generic device groups, both orphan and non-orphan devices have been affected, especially for Class III devices where re-certification was not feasible under the prevailing conditions.

As a result, many of these discontinued devices — though clinically needed — are now effectively "locked out" of the system because Notified Bodies currently refuse to re-accept them as legacy devices, citing the formal cut-off that they were withdrawn prior to May 2021. This regulatory rigidity fails to reflect the real-world clinical value and safe market history of these products.

Therefore, article 120a MDR should be though to be designed as an inclusive grandfathering mechanism — applicable to:

- Orphan devices (as proposed in 3.4), and
- Non-orphan devices with a documented history of safe use and a clear clinical demand — withdrawn pre-2021 due to transitional regulatory barriers.

Such an approach would be consistent with the principles of the US 510(k) pathway, which pragmatically allows reference to safe predicate devices — irrespective of recent market status — as long as no significant changes have occurred.

Ultimately, the goal must be to avoid arbitrary exclusions of valuable technologies purely based on past administrative circumstances, and to restore patient access where there is a justified clinical need and a strong historic safety record.

3.5 Proportionality-based classification of surgical instruments

Proposal/Amendment:

We propose an implementing act on the basis of Article 51(4) MDR, clarifying that reusable surgical instruments are generally to be classified as Class Ir, and an amendment of Article 52(7) MDR to bring reusable surgical instruments under the Ir conformity assessment procedure (mid-term).

More precise, the following bullet points in MDR classification rule 6 (Annex VIII, 5.2) are to be qualified by adding clarifying exceptions:

"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, 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."

We propose to add the following clarification:

"Notwithstanding the above, reusable surgical instruments including reusable endoscopic surgical instruments and rigid endoscopes shall generally be classified as Class Ir.
A deviation to a higher risk class (e.g., Class III) is only justified in exceptional cases, where a device demonstrably involves a significantly higher patient or user risk due to its innovative nature, design characteristics, or specific functional interaction with high-risk tissues or organs.

Such exceptions shall be explicitly listed in a Commission Implementing Act (Annex) in order to provide legal certainty, avoid gold-plating, and ensure proportionality."

Furthermore, we recommend extending the above clarification also to MDR classification rule 7 (Annex VIII, 5.3), which currently classifies surgically invasive devices intended for short-term use as Class IIa, or Class IIb if intended to be placed into a body orifice or surgically created stoma and absorb medicinal products or are used for channeling or storing.

In current practice, many standard surgical instruments — such as clamps, retractors, or forceps — are classified as Class IIa or IIb solely because their typical use in surgery exceeds 60 minutes, although they are reusable, passive, and well-established.

We note that the 60-minute threshold currently applied in Rule 7 as a delineation of transient use is not supported by the state of the art in biological risk assessment. ISO 10993-1, the globally recognized biocompatibility standard, defines "transient" exposure as less than 24 hours, which renders the MDR's 60-minute criterion arbitrary and not risk-based.

Therefore, reusable surgical instruments meeting the definition under Rule 6 — including those used for more than 60 minutes — should not automatically be assigned to a higher risk class under Rule 7.

We propose clarifying in a Commission Implementing Act that for the purposes of Rule 7, reusable surgical instruments with established safety profiles and covered by applicable design and performance standards shall generally be classified as Class Ir, regardless of duration of use.

Justification:

The effort of converting surgical instruments from Class I to Class III — for instance, simple forceps, spatulas, clamps, or scissors — solely due to their intended use in contact with the central nervous or circulatory system is neither proportionate nor risk-based. This regulatory approach leads to an unsustainable burden on manufacturers, especially SMEs, without any measurable improvement in safety for established products and the reality that they can no longer be sold profitably on the market. The consequence is that, on the one hand, the surgical instruments for interventions in neuro- and cardiothoracic surgery are no longer available in Europe to the extent that would be necessary, and, on the other hand, there are no new developments for these critical indications.

Many manufacturers decided to restrict the intended purpose of several surgical products to be used only in the context of general surgical indications – even though this are one and the same products that had been used before MDR in neuro- and cardiothoracic surgery too! The design, materials, manufacturing processes and technical standards applied to such instruments are identical, regardless of their risk classification. Since decades these products are reliable, safe instruments for basic procedures. At this point we would like to refer to the DIN standards of the DIN 58xxxx, DIN 13xxx and DIN 96xxx series which have been in existence for many years.

Global product standards (e.g. for endotoxin levels or particle burden) already ensure that instruments meet tissue-specific safety requirements.

In addition, specific requirements for the products used in central nervous system and central circulation system are fulfilled by the application of global standards anyways by the legal manufacturer (e.g. endotoxine load, particle loads). Fulfilling these risk-mitigating specifications for the tissue-specific risks means that tissue-specific safety of the product is given by the design and manufacture of the product[13].

For comparison: Under the FDA, almost all reusable surgical instruments are considered class I, regardless of whether they are used on the central nervous system or the circulatory system. We recommend the same approach for surgical instruments (e.g. tissue spatulas).

[13] See 2007/47 recital 22

Further examples — including forceps, chisels, retractors, clamps, palpation hooks, hammers and more — particularly products without direct wound contact (e.g., dressing scissors, kidney dishes, drape clamps) can be found in **Annex II** of this proposal. Moreover, for many such surgical instruments, no published clinical data exists, implicitly forcing manufacturers to conduct clinical studies. This is problematic, as no new insights can realistically be expected for such well-understood instruments, even if studies were carried out.

Let us give an exemplary illustration to visualize:

Surgical scissors

Example of Class Ir application: General surgery

Example of Class III application: Neurosurgery (when opening the dura mater)

A reality that cancels out the purpose of the MDR: Due to the lack of appropriately classified instruments on the market, physicians increasingly resort to off-label use of Class Ir instruments in high-risk settings such as neurosurgery or cardiothoracic procedures. This results in significant liability risks for users and legal uncertainty across Member States. In Germany, for example, national law says: “Medical devices may only be operated and used in accordance with their intended purpose (...) and the generally accepted rules of technology”. Yet there is often no practical alternative available to clinicians. Legal manufacturers have no way to intervene or prevent such usage. In such situations, health care professionals weigh the legal risk of off-label use as less severe than the ethical and legal risk of failing to provide necessary care to the patient. This ethical dilemma for physicians must be openly acknowledged. This reality contradicts the very purpose and ethical foundation of the MDR.

At the same time, we caution against creating a flat-rate downgrading rule but differentiation. There may be reusable rigid endoscopes, endoscopic reusable instruments or surgical instruments — especially innovative, complex, or system-integrated products — for which a higher classification is justified due to design novelty or specific clinical risk. These must, however, remain well-documented exceptions and be explicitly listed in the implementing act's annex.

Conclusion:

A harmonised reclassification of rigid endoscopes, endoscopic surgical instruments and reusable surgical instruments to Class Ir, paired with an exception list in a Commission Implementing Act, would:

- Reduce unjustified regulatory burdens and restore market access
- Prevent "off-label workarounds" and liability risks for clinicians
- Ensure safety via adherence to global standards
- Protect innovation and access to care in high-risk specialties
- Preserve legal clarity and room for justified exceptions

Further examples of currently over-classified products (e.g. simple surgical scissors, suction devices, fusion cages) can be found in Annex II of this proposal.

We would also like to point out that there are also some non-active medical devices in class IIa, such as simple surgical suction devices, which are also surgically invasive, reprocessable instruments and should belong in class Ir too, even if they are connected to an active pump in class IIa.

Examples of further nonsensical high classifications in class III under MDR can also be found in classification rule 8, e.g. for fusion cages, which were risk class IIb under the MDD (also see Annex II). They should belong to class IIb for their inherent risk also under MDR.

4 CALL TO ACTION

The EU Medical Device Regulation (MDR) was introduced to strengthen patient safety and improve the quality of medical devices. However, in practice, it has created unintended and disproportionate burdens, particularly for low-risk legacy products and small to mid-sized manufacturers.

The current framework imposes rigid conformity assessment practices, excessive clinical documentation, redundant audits, and complex post-market requirements — often without measurable safety benefits. This is especially evident in cases involving well-established technologies (WET), where the lack of practical implementation guidance blocks the use of long-proven devices.

The proposals in this paper seek to realign regulatory expectations with actual risk, medical need, and innovation capacity. By enabling targeted exemptions, risk-based approaches, and a functional WET framework, we aim to restore the MDR's credibility and effectiveness — while preserving the diversity, safety, and accessibility of medical technologies in Europe.

The European Commission must act — swiftly, pragmatically, and in coordination with stakeholders:

- To safeguard access to essential medical technologies.
- To restore legal clarity and reduce unnecessary complexity — especially for SMEs.
- To make the MDR fit for the realities of healthcare delivery and the pace of innovation.

Ultimately, this is about much more than compliance. It is about preserving Europe's technological sovereignty, its global leadership in medical innovation — and above all, about ensuring that patients across the EU have timely access to safe, effective, and proven medical technologies.

At MedicalMountains, we do not simply highlight problems — we provide workable, industry-supported solutions:

- Fully aligned with high safety and performance standards.
- Supported by both large and small manufacturers.
- Designed to relieve unnecessary burden without compromising patient safety.

5 ANNEX I – PRODUCT SUGGESTIONS FOR A SIMPLIFIED CLINICAL EVALUATION

Medical Device
Bowls
Cables high frequency
HF handles
Light carriers
Cables for medical devices (for generators, extraction systems, vacuum cleaners, etc)
Cast cutters, line-powered
Chisels
Clamps
Curettes
Diagnostic reusable instruments: - Head reflectors - Tuning forks - Laryngeal mirrors
Elevatoren
Endo instruments Laparoscopic needle holders are intended for suturing in the pneumoperitoneum. They are intended for grasping and holding surgical suture material. Semi-rigid and flexible biopsy forceps, grasping forceps, scissors, and flexible stone removers are intended for cutting, grasping, and removing biopsies or stones in endoscopic gynaecology/urology. Optical punches and forceps are intended for cutting tissue and taking biopsies in endoscopic gynaecology/urology.
Trocar spikes and obturators Shafts are intended for suction, irrigation, insufflation, and/or the insertion of instruments during minimally invasive surgical procedures. Obturators are intended for the gentle insertion of shafts during endoscopic procedures in gynaecology and urology. Trocar spikes are intended to create a controlled entrance for the insertion of endoscopic instruments into the human body. Arthroscopic irrigation cannulas and their trocar spikes/obturators are intended for opening and irrigation of the surgical area. The safety trocar spike is used for laparoscopic access through the abdominal wall.
Pliers (clamping pliers, grain pliers, swab pliers, sponge pliers) Nail nippers Grip, round, flat and parallel flat pliers as well as wire pliers
Haemorrhoid ligators

Medical Device
Hooks and picks (also in relation to spinal implants)
Mallets
Manual surgical rotary handpieces
Mouth gags, tongue depressor
Mouth prop, plastic coated metal frame, without chain and with chain
Mouth mirrors
Snares
Needle holders
Probes and dilators
Punches, skin trephines, bone forceps, rongeurs, septum forceps
Retractors such as wound and skin hooks, abdominal flap holders (handheld), nasal wing hooks, nerve root hooks, thyroid hooks, ramus hooks, bladder spatulas, prostate hooks, and birthing spoons
Retractors self-retaining
Saws, surgical
Scalpel and knives, reusable
Scissors in all variants
Shears and cutters
Spatulas
Speculums
Sterilization containers and filters, indicators
Urethrotomes
Trays
Callipers, rulers
Syringes
Tweezers
Light Sources (Established techniques, e.g. cold light sources)
Rigid endoscopes (laryngoscopes, arthroscopes, laparoscopes, hysteroscopes, cystoscopes, sinuscopes, otoscopes, ...)
Flexible Nasopharyngoscopes (class I, with glass fibre image bundle or image sensor)
Equipment trolleys and holding systems
Dermatomes
Camera systems including camera heads, cold light sources (class I, operating in the visible spectrum), recording and memory devices
Bone carrier for artificial bone material
Bone mill
Scaler

6 ANNEX II – PRODUCT EXAMPLES FOR RECLASSIFICATION UNDER RULES 6, 7 AND 8

The following products are currently subject to inconsistent classification depending on indication (e.g. general vs. neurosurgery). All instruments listed below are identical in design and manufacturing and should consistently be classified as Class Ir, unless they are active or implantable:

Medical Device
Suction cannula [Class IIa only because it is connected to a tube from a saliva suction device. However, no energy flows through it, it is just a stainless-steel tube]
Electrosurgical instruments
Basically, all reusable, invasive surgical instruments for the application on brain (neurosurgical) and central nervous system (spine) and in heart surgery for up to 24 hours: - Scissors - Biopsy forceps - Probes - Hooks (nerve/vessel) - Spatula - Dissectors, enucleator, raspatorium - Elevators - Vascular dilators - Surgical knives - Forceps, grasping forceps - Blades - Bone Spoons and curettes - Needle holders - Grasping forceps - Clamps - Vascular Clips, Bulldog - Artery clamps. Ligature clamps - Scalp clips - Retractors - Micro spring scissors (Ir for ENT; III for neurosurgery) - Bayonet micro forceps (Ir for ENT; III for neurosurgery) - Microdissectors (Ir in microsurgery; III in neurosurgery) - Tissue spatula (Ir for general; III for neurosurgery)
All implants that serve to fuse bones [under MDD risk class IIb, under MDR III]: - Spinal disc replacements (fusion) - Cages (fusion) - Implant systems for fusion Further explanations: The Australian Classification Guidelines have formulated the exceptions to product classification as follows: “Ancillary devices, such as screws, plates, hooks and rods intended for use during spinal fusion procedures, and in procedures preserving mobility, remain Class IIb, as long as they are not explicitly used in preserving the motion of the spine. (If the device is intended by the manufacturer to be a motion-preserving device for the spine (such as a spinal disc replacement), the device is classified as Class III.)”