The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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MDR/IVDR revision: impact on the sector

Executive Summary

The proposed revisions to the MDR and IVDR offer opportunities to improve predictability, transparency and efficiency in conformity assessment. Notified Bodies (NBs) broadly support these objectives and recognise that MDR/IVDR have already strengthened quality, clinical evidence, and compliance across the sector.

However, several concerns remain. Key regulatory foundations—particularly EUDAMED and Common Specifications—are still incomplete. Proposed reductions in scrutiny risk weakening oversight to levels below those under the former Directives, with potential implications for patient safety, trust and market supervision. In addition, assumptions made in the Commission's estimated €2.1 billion cost savings do not reflect the actual scale of NB revenues and therefore appear unrealistic.

Team-NB supports measures that genuinely reduce administrative burden, promote innovation, and enable earlier regulatory dialogue. At the same time, any reforms must safeguard patient safety and maintain robust oversight.

1. Introduction

Team-NB, the European Association of Medical Devices Notified Bodies, fully supports the objective of improving predictability, consistency and transparency in conformity assessment. MDR and IVDR have already delivered significant improvements, and this trajectory is set to continue, particularly with the anticipated rollout of EUDAMED.

Notified Bodies observe daily benefits:

– Better-structured technical documentation
– Stronger clinical evidence
– A more mature quality and compliance culture among manufacturers

The proposed revisions represent an opportunity to refine the system, strengthen its coherence and ensure it remains fit for purpose and patient-centred.

2. Positive Elements in the Proposed Revisions

2.1 Digitalisation and Data-Driven Processes

Team-NB welcomes the shift towards data-driven digital technical documentation, electronic labelling, declarations of conformity and certificates. Combined with EUDAMED and remote audit tools, these measures can improve transparency, support audit planning and reduce administrative burden.

2.2 Earlier Regulatory Dialogue and Expert Involvement

Strengthened interactions between manufacturers, NBs, MDCG and expert panels will support high-quality assessments and more timely access to safe devices. Inclusion of NB experts in relevant structures and reinforced reporting requirements are positive steps.

2.3 Streamlined Pathways for Innovation

Clarifications on qualification and classification, regulatory sandboxes, combined studies, and specific routes for orphan and breakthrough devices will support innovation, provided that evidence requirements remain clear and proportionate.

3. Key Concerns

3.1 Risk of Reduced Regulatory Scrutiny

Several proposed changes would reduce oversight to levels below those previously applied under the Directives. These include reductions in:

– QMS audits
– Technical documentation sampling
– Unannounced audits
– Review of vigilance data, SS(C)P and PSUR
– Requirements for implant cards and public information (e.g. SSCPs)
– Re-certification and expiry dates

Reduced scrutiny may create short-term administrative relief but can undermine patient safety, weaken market trust and require substantially increased market surveillance resources from competent authorities.

3.2 Need for Clarification of Core Definitions

Clear definitions are essential for consistent implementation. Key areas or terms requiring clarification include:

– Well-established technologies (WET)
– Basic UDI-DI
– Generic device group
– Article 61(10)

– Equivalence criteria
– Dispute-handling mechanisms (e.g., ombudsman)
– rolling review
– similar device
– clinical outcome

The apparent re-introduction of Own Brand Labelling (OBL) raises concerns regarding access to underlying technical documentation.

3.3 Unrealistic Assumptions in Cost-Savings Estimates

The Commission's estimated €2.1 billion in savings for conformity assessment activities[1] significantly exceeds the total revenue of all NBs combined (€475 million in 2024, see table 1). Even substantial reductions in NB activity could not produce savings of this magnitude without severely compromising oversight.

Table 1: Total revenue for Notified Bodies (2024)

QMS certificates	219 millions €
Product certificates	256 millions €
Total 50 NBs revenue in 2024	**475 millions €**

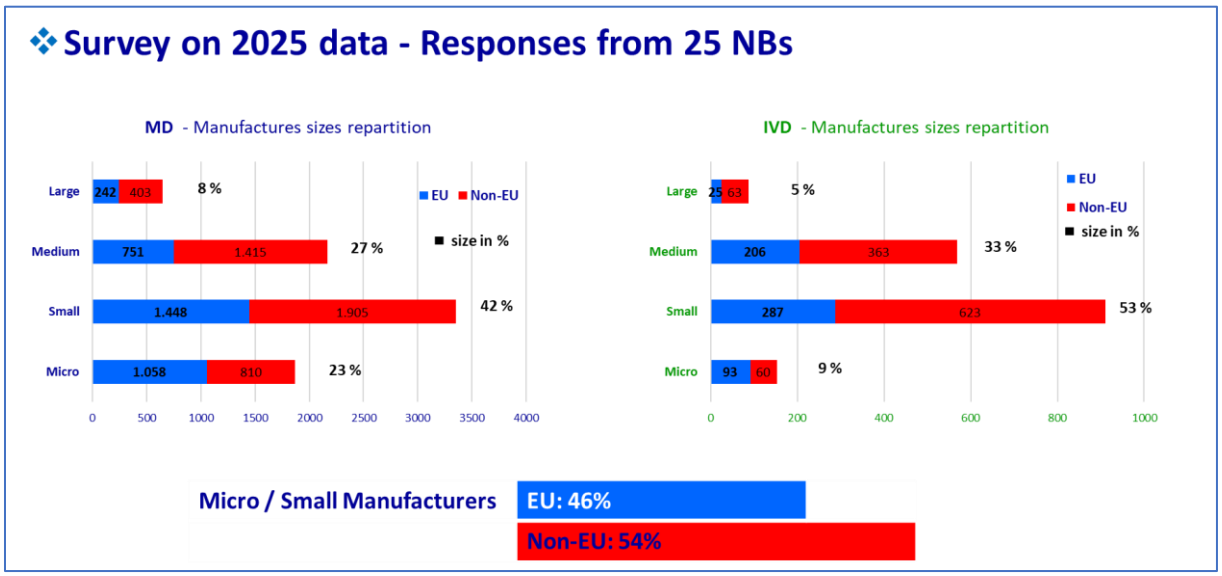
NB activities represent approximately 0.28% of the €170 billion EU MedTech market[2]. Even a large percentage reduction in NB work therefore has negligible impact at system level but substantial impact on regulatory control.

3.4 Impact on Non-EU Manufacturers and EU Market Attractiveness

Data from Team-NB members shows that a substantial proportion of MDR/IVDR certificates in 2025 were issued to manufacturers located outside the EU, and that **more than half of the micro and small manufacturers placing devices on the EU market are non-EU based**. (see figure 1)

[1] European Commission (2025). Commission proposes targeted simplification of medical devices rules to improve efficiency and competitiveness. Press Release, 16 December 2025. Available at: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en
[2]European Commission (2025). Factsheet: Key Elements of the Targeted Revision of the MDR and IVDR. Published 16 December 2025. Available at: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Figure 1: EU vs non-EU based manufacturers



The proposal introduces obligatory and considerable **discount on Notified Body fees for micro and small manufacturers**, regardless of whether they are established inside or outside the EU. While the intention—to support smaller companies—is understandable, several unintended consequences should be considered:

Potential negative consequences for EU competitiveness

- Offering the same discount to non-EU micro and small manufacturers may further incentivise non-EU companies to enter the EU market, potentially intensifying competitive pressure on EU-based SMEs rather than supporting them.
- As a result, the measure may become counterproductive to the stated goal of strengthening the competitiveness of manufacturers within the Union.

Negative implications for Notified Bodies

- A large proportion of micro and small manufacturers served by Notified Bodies are located outside the EU and this number could increase. Applying mandatory fee reductions across this category would significantly reduce NB revenue, without reducing the underlying assessment workload.
    - Conformity assessment effort is driven by device risk class, technical documentation quality and clinical evidence requirements, not by company size or location. For NBs, the effort of evaluating a device from a micro or small manufacturer is often equal to, or sometimes even greater than for larger manufacturers due to e.g., less mature quality systems, more frequent nonconformities, greater need for clarification and longer reaction times.

- The mandatory discount would therefore create an imbalance between required effort and compensated cost, potentially affecting NB sustainability—particularly since **many NBs are themselves SMEs.**
- Reduced NB financial stability could ultimately weaken the capacity and resilience of the conformity assessment system, contradicting the policy objective of strengthening regulatory performance.

In summary, while supporting micro and small manufacturers is an important objective, the proposed discount mechanism risks distorting competition, unintentionally benefiting non-EU manufacturers, and placing additional financial strain on Notified Bodies. Alternative support mechanisms—targeted, proportionate and linked to demonstrated need—would be more effective and more aligned with the Union's strategic objectives.

4. Implementation Challenges

Efficient implementation will be hindered by the volume and timing of proposed changes. Several previously initiated reforms—such as EUDAMED, Common Specifications, and MDCG guidance consolidation—are still underway. Introducing new rules with short transition periods risks generating uncertainty and slowing innovation.

5. Conclusion

Notified Bodies are supportive of many elements of the proposed revisions, particularly those aimed at enhancing predictability, improving regulatory dialogue, supporting digitalisation and streamlining innovative pathways

However, major reservations remain regarding reduced scrutiny, unrealistic cost-saving assumptions and the potential unintended effects on patient safety and market functioning.

The MDR and IVDR have significantly strengthened the safety, quality and performance of medical devices and diagnostics in the EU. The upcoming revision offers an opportunity to reinforce these achievements by improving efficiency, consistency, and clarity.

To achieve this, reforms must be evidence-based, realistic, and implemented at a pace that supports—not disrupts—the system. Safeguarding patient safety should remain the primary objective, and reductions in oversight should only be considered where supported by solid data.

Team-NB remains committed to constructive cooperation with EU and national institutions and stakeholders and stands ready to contribute expertise to a balanced and sustainable regulatory framework.