

Revising the Medical Device Regulatory Framework: Team-NB's Concerns and Proposed Solutions

The European Association of Medical Devices Notified Bodies (Team-NB) fully supports the objectives of the Commission's proposal for revision of the current MD and IVD Regulations (MDR and IVDR) which aim to "establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation".

Nevertheless, Team-NB considers that further political attention would be beneficial in addressing several areas of the regulatory framework that could have existential consequences for the sector. The four most pressing concerns are set out below, together with a concrete solution proposed by Team-NB for each. The choices made by European policymakers will be instrumental in safeguarding the long-term sustainability and global competitiveness of the medical device sector and, above all, in ensuring that patients continue to benefit from timely access to safe and effective medical technologies.

1. Patient Safety

The proposal and amendments continue to scale back Quality Management System audits, Technical Documentation sampling, unannounced audits, expiry dates on certificates and many other opportunities to be proactive in conformity assessment. There has been no impact assessment to assess the cumulative impact of these changes and a move to reacting to safety problems. This omission limits the full understanding of the economic, organisational and healthcare effects of the proposed actions, including the opportunity to compare them with possible alternatives.

Our proposal for risk-adaptive surveillance is balanced, proportionate and evidence-based and will ensure that devices placed on the market are safe, effective, and performing as intended.

Risk-adapted surveillance in the framework of the MDR/IVDR proposed revision of the Regulations – published on July 31st

Link: <https://www.team-nb.org/wp-content/uploads/2026/08/Team-NB-RiskAdaptiveSurveillance-presentation-20260724.pdf>

2. Transparency

Our proposal to allow the Notified Bodies visibility of EUDAMED has not been considered in any proposed amendments.



Transparency is the enabling condition for any residual safety mechanism. Even with a reduced set of audits, Notified Bodies need reliable, timely data to decide where to focus their limited resources. Without EUDAMED access, we cannot apply risk-adaptive surveillance effectively.

Notified Bodies are subject to the same confidentiality requirements as the Member States, and we are willing to sign further declarations to enhance this imperative.

Position Paper on Transparency in the framework of the MDR/IVDR proposed revision of the Regulations – published on August 6th

Link : <https://www.team-nb.org/wp-content/uploads/2026/08/Team-NB-PositionPaper-Transparency-V1-20260806.pdf>

3. Clarity of definitions

The additional conformity-assessment routes proposed for orphan and well-established-technology (WET) devices still hinges on vague definitions. The draft definitions of WET, together with wording such as ‘where appropriate’ and ‘if applicable’, are likely to lead to inconsistent interpretation, reduce predictability and generate administrative inefficiencies.

Our proposal links WET status to the availability of harmonised standards or common specifications and that defines the “where appropriate/if applicable” triggers through clear quantitative thresholds (e.g., market-share > 5 %, ≥ 10 years EU presence, no serious adverse events in the last 3 years). This matrix would be incorporated into the MDR/IVDR annexes and would be subject to a public consultation before final adoption.

4. Capacity concerns and fee measures

Mandatory small and medium enterprises (SME) discounts, combined with deferred payment until certificate issuance, would force Notified Bodies to finance assessments at reduced fees and absorb client default risk, which runs highest among SMEs. The resulting cash-flow strain could make Notified Bodies more cautious about taking on SME clients, the opposite of the measure's intent. Tying payment to certification would also compromise the impartiality the MDR requires.

Rather than blanket percentage cuts, we propose a public funding or innovation support scheme for SME manufacturers, building on existing MDCG guidance for orphan devices and breakthrough (BtX) pathways.

We also warn against granting the Commission broad power to set the structure and level of Notified Body fees by implementing act without a dedicated impact assessment of its effects on the functioning and capacity of the conformity assessment system. Any intervention in fee structures directly affects Notified Bodies' ability to sustain capacity and could lead to fewer specialised entrants, longer queues, and reduced availability of devices for patients.

The EU Notified-Body sector employs roughly 6 000 specialists. Team-NB, representing this community, remains committed to all of the objectives of the targeted revision and the future MD/IVD legislation – simplification, streamline and proportionate requirements, no duplication, support for innovation, breakthrough, orphan and paediatric devices, enhanced digitalisation and our full competent and impartial technical and clinical expertise contributing to EU-level scientific support.

While we are awaiting the changes to the legislation, Team-NB would welcome additional initiatives to meet the objectives, such as streamlining the designation codes, completing the mapping to MDSAP to allow efficient use of resources and international simplification and updates to the MDCG guidance to allow more risk-based sampling, enhanced communication to facilitate innovative SMEs and Notified Bodies involvement in the pilot projects with the expert panels.

Team-NB emphasise that it actively supports the improvement of the regulatory framework in the medical devices sector to meet the legitimate expectations of the Public Health for the well-being of the population.

In case of any further clarification needed, please contact schlemmer@team-nb.org