The European Association of Medical devices Notified Bodies

Team-NB Presentation

Briefing Note: Risk-Adaptive Surveillance under the MDR/IVDR

Purpose: This note explains Team-NB's proposal for risk-adaptive notified body surveillance. It shows how simplification can reduce unnecessary burden while maintaining patient safety and effective oversight.

The problem

Medical devices need continued monitoring after they are placed on the EU market. The key question is not whether surveillance should continue, but how it can become more proportionate. A blanket reduction would create safety risks. A smarter model reduces routine oversight where there is evidence that the manufacturer and its devices are performing well.

What risk-adaptive surveillance means

- Higher oversight where risks, new concerns or weak compliance are present.
- Lower routine oversight where stable compliance and post-market performance are demonstrated.
- Immediate escalation if serious incidents, recurring non-conformities, poor responsiveness, negative vigilance trends or other safety signals arise.

Policy value

- Keeps patient safety central while reducing unnecessary routine checks.
- Focuses notified body capacity on higher-risk manufacturers, devices and situations.
- Rewards well-performing manufacturers with less routine oversight, potentially reducing notified body effort and manufacturer compliance costs.
- Avoids a purely reactive system where additional checks occur only after problems have arisen.

Fairness to early MDR/IVDR adopters

The first MDR certificates were issued in 2019 and the first IVDR certificates in 2020. Manufacturers that moved early to MDR/IVDR compliance have had several years to build evidence of conformity, post-market performance and quality system stability. Risk-adaptive surveillance allows these early adopters to be recognised where the evidence supports it, rather than being treated the same as manufacturers that waited until the end of the transition periods.

Key message

Risk-adaptive surveillance focuses scrutiny where risks are higher, rewards proven compliance, and keeps patient safety at the centre.

Sources: Team-NB Position Papers on Risk-Adaptive Surveillance under MDR and IVDR (30 June 2026). Available via the Team-NB website: MDR proposal and IVDR proposal.