The European Association of
Medical devices Notified Bodies

Team-NB Presentation

Briefing Note: Transparency under the MDR/IVDR

Purpose: To explain why notified bodies need broader EUDAMED access to support proportionate, risk-adaptive surveillance under the MDR and IVDR, while preserving confidentiality of sensitive information.

The problem

The Commission proposal gives notified body access to EUDAMED information for devices for which they issue certificates. It does not, however, provide broader visibility of vigilance, clinical investigation and performance study data for comparable devices certified by other notified bodies. This creates an incomplete EU-market picture: notified bodies can assess their own certification portfolio, but cannot reliably benchmark risks, adverse events, field safety corrective actions or state-of-the-art developments across comparable technologies. In practice, this may lead to reliance on non-EU public databases, duplicate requests to manufacturers and surveillance decisions based on partial evidence.

What broader EUDAMED transparency should provide

- EU-wide visibility of relevant vigilance data, including serious incidents, field safety corrective actions, field safety notices and emerging safety trends for comparable devices.
- Access to clinical investigation and performance study information needed to assess state of the art, comparable technologies and relevant adverse events.
- A stronger evidence base for risk-based decisions on technical documentation sampling, surveillance intensity and unannounced audits.
- Clear confidentiality rules so data accessed through EUDAMED are used only for regulatory purposes and protected against inappropriate onward disclosure.

Policy value

- Enables notified bodies to benchmark risks against the wider EU market, not only their own certification portfolio.
- Reduces duplicate information requests where data are already available in EUDAMED.
- Supports consistent escalation where signals justify additional scrutiny and reduced routine burden where compliance is stable.
- Strengthens patient safety by making surveillance more targeted, evidence-based and proportionate.

Link to Team-NB amendments

This is reflected in Topic 5 of the Team-NB amendments, “Transparency of EUDAMED”. Team-NB proposes broader notified body access to EUDAMED vigilance and clinical investigation/performance study information, accompanied by confidentiality safeguards in MDR Article 109, IVDR Article 102 and Annex VII. This balances better regulatory use of data with protection of confidential information.

The European Association of
Medical devices Notified Bodies

Team-NB Presentation

Key message

The issue is not whether notified bodies can see the devices they certify; they can. The issue is whether they can see enough EU-wide evidence to make surveillance genuinely risk-adaptive.

Sources: Commission proposal COM(2025) 1023 final; Team-NB amendments for MDR/IVDR, Topic 5 “Transparency of EUDAMED”, including proposed amendments to MDR Articles 92(2), 106b and 109, MDR Annex VII 1.3.1, IVDR Articles 82a, 87(2) and 102, and IVDR Annex VII 1.3.1. – See page 24 of attached document.