Medical Device & *In Vitro* Diagnostic Medical Device Regulations – EU State of Play

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Agenda

1. Commission proposal to revise and simplify the MDR/IVDR (MDR / IVDR 2.0)
2. Implementation activities

1. Commission proposal to revise and simplify the MDR/IVDR (MDR / IVDR 2.0)

MDR/IVDR simplification proposal

COMMISSION PROPOSAL • 16 DEC 2025

- **Maintain high level of patient safety**
- **Reduce unnecessary regulatory burden**
- **Make the framework more proportionate**
- **Optimise scarce regulatory resources**
- **Enable flexibility for special needs and shortages**

Regulatory effort should be proportionate, risk-based and focused on the areas that matter most for patient safety.

The safeguard architecture

1. Safety backbone

Manufacturer duties, device requirements and life-cycle obligations remain intact.

2. Risk-based oversight

Fixed procedures give way to escalation, scrutiny and targeting where evidence or risk requires it.

3. Special patient needs

Availability, orphan/breakthrough access, in-house flexibility and emergency routes are reinforced.

SAFEGUARD 1

The safety backbone remains

We simplify how we regulate, not what we require – patient safety stays our top priority.

High standards of safety and performance are preserved as the foundation of the MDR and IVDR.
Move from fixed procedures to risk-based oversight

1. Proven safety framework

Our strong safety culture continues.

2. Robust requirements maintained

Manufacturer obligations and device requirements under the MDR and IVDR remain fully intact.

3. Life-cycle approach

From design and clinical evidence to post-market surveillance – safety across the entire lifecycle.

4. Targeted changes only

Very few and targeted changes in oversight for high-risk devices.

5. Post-market emphasis

Continued focus on vigilance, market surveillance and corrective actions.

6. Same safety outcome

Simplification does not mean lowering standards – it means achieving the same high level of protection more efficiently.

Safety and performance requirements remain the non-negotiable foundation.

SAFEGUARD 2

Strong risk-based oversight

Focus regulatory effort where risks are highest

MORE PROPORTIONATE & RISK-BASED

Less administrative burden for low-risk devices
e.g. removal of some performance study and clinical investigation authorisation requirements.

Shift from fixed-frequency to risk-based monitoring
e.g. removal of systematic technical documentation sampling for medium-risk devices.

Reduced routines over time
e.g. reduced frequency of PSUR after 1st year, as long as the device remains in benefit-risk balance.

MECHANISMS TO ADDRESS RISKS

Scrutiny when issues arise
Notified bodies may increase scrutiny if issues are detected, including requests for technical documentation.

Linked to track record
Simplifications apply when manufacturers and devices have a good record of compliance.

Stronger coordination
Enhanced Member State coordination for vigilance and market surveillance.

✓ **Optimised use of regulatory resources → more effective oversight.**

SAFEGUARD 3

Protection of special patient needs

Flexibility to respond to special needs and situations → foster innovation and secure availability.

Pathways for innovation
Support for breakthrough and orphan devices through tailored pathways.

Legacy & orphan devices
Safeguards to maintain availability of legacy or orphan devices.

Device availability
IT system to anticipate and monitor shortages; critical devices list and supply-chain information.

Regulatory sandboxes
Possibility to support innovative devices via national & union regulatory sandboxes.

Derogations framework
Expanded and clearer framework for derogations from conformity assessment.

Member State coordination
Reinforced cooperation on derogations for a swift and consistent response.

Ensure patients continue to have timely access to innovative and essential devices

MDR/IVDR revision: looking ahead

2. Implementation activities

Breakthrough Technologies (BtX)

Breakthrough Technologies - **Pathway**

MDCG 2025-9

EU structured framework for recognition and early regulatory support for breakthrough technologies

Expert panel opinion

Manufacturers may request an expert-panel opinion on whether the device meets BtX criteria.

NB prioritisation

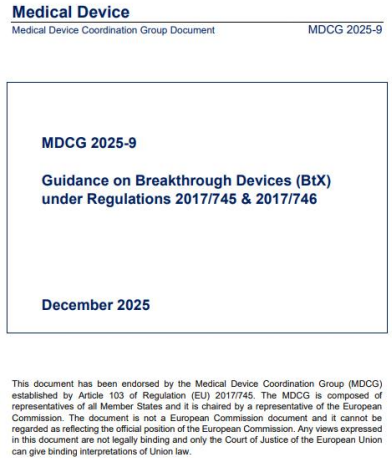
Notified bodies should prioritise BtX and provide access to structured dialogue where appropriate.

Early advice

Expert panels may advise on clinical development, performance evaluation, non-clinical data and regulatory-scientific questions.

Conditional certification logic

NBs may define specific conditions, including PMCF/PMPF milestones and enhanced surveillance.



Medical Device

Medical Device Coordination Group Document MDCG 2025-9

MDCG 2025-9

Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746

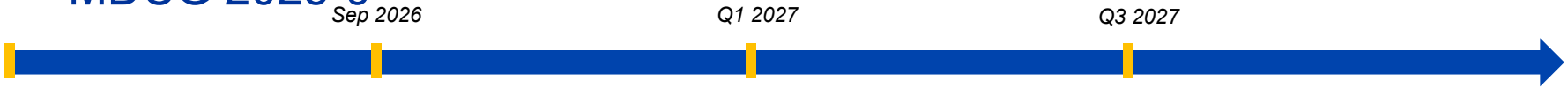
December 2025

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

The value of BtX status lies in earlier, more coordinated regulatory-scientific interaction — especially around evidence planning.

Breakthrough Technologies - **Pilot**

MDCG 2025-9



PHASE IA

Test 6 priority procedures

- 1 per manufacturer
- 1 ready for conformity assessment
- Priority to paediatrics & cardiology

DEVICE SCOPE

Class III + Class IIb AARMP

PHASE IB

Extend to all other procedures in remit

DEVICE SCOPE

Class III + Class IIb AARMP

PHASE II

Expand to all medical device classes

DEVICE SCOPE

All medical device classes

PHASE III

Expand to IVDs

DEVICE SCOPE

All medical device classes + IVDs

GOVERNANCE Expert panels + National Competent Authorities; notified body participation in the advice step

Eudamed

EUDAMED: **operational & mandatory**

Mandatory use of first four modules from 28 May 2026

Why it matters

Shift from temporary/voluntary architecture to mandatory regulatory data flows. EMDN, UDI, certificate visibility and market surveillance now become everyday infrastructure.

Actors

who is in the system

UDI / Devices

what is on the market

NBs & Certificates

what has been certified

Market Surveillance

authority visibility

Pending

Vigilance/PMS and clinical investigations/performance studies are not yet mandatory modules;.

Notified body requirements (Annex VII)

Notified body requirements

Annex VII implementing act

The system introduces more predictability by design and harmonises procedural practices across notified bodies.

Quotations & scope

Common input information and clearer estimates of cost, duration and assessment scope.

Timelines & clock-stops

Maximum timelines, justified interruptions and fewer open-ended delays.

Re-certification

Focused and based on lifecycle evidence, not a full repeat of initial certification activities.

Monitoring & reporting

NBs monitor duration/costs and publish comparable annual performance information.

Notified body requirements

Annex VII implementing act: changes in the assessment journey

Cost transparency | **Time discipline** | **Public accountability**

Faster and more consistent procedures must support — not replace — robust assessment of safety and performance.

1 → 2 → 3 → 4 → 5

Pre-application / quotation

Harmonised information package; transparent scope, cost and timeline estimates.

Application review

Clearer starting point for assessment and contract planning.

QMS + technical assessment

Defined maximum durations and controlled interruptions.

Decision / certificate

More predictable closure and issuance of certificate or supplement.

Re-certification

Focused lifecycle-based renewal, avoiding unnecessary repetition.

Well-Established Technologies (WET)

Well-established technologies

Mature technologies with a long safety record are treated more proportionately while the MDR evidence backbone remains intact.

The system recognises proven, mature devices **without** waiving clinical evaluation, technical documentation, PMS or conformity assessment responsibilities.

1 Why WET can be treated differently

- Simple, common and stable design with little evolution;
- Well-known safety and no safety issues;
- Well-known clinical performance and standard of care;
- Long history on the market.[1]

2 What is preserved

- Manufacturers still need sufficient clinical evidence,
- MDR-compliant clinical evaluation and lifecycle evidence.

3 What becomes proportionate

- Some automatic or repetitive procedures are replaced by targeted assessment and documented justification.

[1] As defined in MDCG 2020-6.

Well-established technologies (WET)

Delegated Regulation (EU) 2026/1359

Article 52(4)

Class IIb implantable devices

What changes Notified body no longer needs to assess the technical documentation of every individual device type listed as WET.

What remains Conformity assessment, full technical documentation, QMS requirements, PMS and vigilance remain — the change is the intensity/frequency of NB review.

From per-device assessment → targeted technical-documentation sampling

Delegated Regulation (EU) 2026/1451

Article 61(6)(b)

Implantable + Class III devices

What changes For listed device types, a new device-specific clinical investigation is not automatically required if conditions are met.

What remains Clinical evaluation still requires sufficient clinical data and compliance with relevant common specifications, where available; justification must be documented.

From automatic clinical investigation → evidence-based clinical-evaluation decision

Thank You!

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