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5-minute guide to:

EU proposal to simplify MDR & IVDR

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On 16 December 2025, the European Commission published a proposal to amend the EU regulatory framework for medical devices and in-vitro diagnostic medical devices.

The objective is to **simplify existing rules**, **reduce administrative burden**, **improve predictability**, and **support innovation and competitiveness**, while maintaining a high level of patient safety and public health protection.

The proposal amends:

Regulation (EU) 2017/745 (MDR)

Regulation (EU) 2017/746 (IVDR)

It follows an evaluation of MDR and IVDR implementation, including stakeholder consultations and a call for evidence.

Feedback consistently highlighted excessive administrative burden, lack of predictability, and negative impacts on innovation and device availability, especially for SMEs.

Key elements of the proposal

Reduction of administrative burden

The proposal seeks to streamline reporting and documentation requirements and eliminate unnecessary or duplicative obligations, especially where they create disproportionate workload without adding safety value.

Improved predictability & efficiency

Changes aim to make conformity assessment and regulatory timelines more transparent and predictable, addressing bottlenecks and delays experienced under MDR and IVDR.

Proportionality of requirements

Regulatory obligations are intended to be better aligned with device risk classes, reducing complexity for low and medium risk devices where appropriate.

Digitalisation

Greater use of digital tools and systems is encouraged to replace paper-based processes and improve data use, including better functioning of EU-level databases.

Support for innovation & SMEs

Simplification and clarification are expected to lower barriers for innovation, particularly benefiting small and medium-sized enterprises and growth-stage companies.

Maintained safety standards

The proposal explicitly preserves high standards for patient and user safety and does not lower core safety or performance requirements.

Legislative process & indicative timeline

Q1 - Q2 2026

- Review by the EU Parliament and Council
- Appointment of rapporteurs, committee discussions, and proposed amendments

Q3 - Q4 2026

- Adoption of positions by Parliament and Council
- Trilogue negotiations to agree on a common text

Late 2026 - Early 2027

- Final adoption by Parliament and Council
- Publication in the Official Journal of the EU

2027

- Entry into force (typically 20 days after publication)

2027 - 2028 & beyond

- Transitional periods for implementation
- Issuance of guidance documents and practical application by manufacturers and authorities

Practical implications

Short-term (2026)

- No immediate legal changes, but strategic relevance for regulatory planning

Mid-term (2027)

- First legally binding simplifications take effect

Long-term (2027 - 2028+)

- Operational relief through reduced administrative burden, clearer timelines, and more digital processes

Should you have a regulatory challenge, our team is ready and happy to help. Simply get in touch to start the conversation.

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