New European Commission Delegated Regulations on Medical Devices

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On 29 June 2026, the European Commission published two delegated regulations expanding the exemption lists provided for in Regulation (EU) 2017/745 on medical devices ("MDR").

- Commission Delegated Regulation (EU) 2026/1359 ("Regulation 2026/1359"), expanding the list of class IIb implantable devices exempt from the obligation to carry out a technical documentation review, within the conformity assessment procedure;
- Commission Delegated Regulation (EU) 2026/1451 ("Regulation 2026/1451"), expanding the list of implantable devices and class III devices exempt from the obligation to conduct clinical investigations.

Both regulations were adopted on 20 March 2026 and enter into force on 19 July 2026.

I. Commission Delegated Regulation (EU) 2026/1359 of 20 March 2026

Regulation 2026/1359 amends the MDR as regards the list of class IIb implantable devices exempt from the obligation to carry out a technical documentation review for each device, within the conformity assessment procedure set out in Annex IX, Section 4.

Article 52(4) of the MDR establishes that, for class IIb implantable devices, the technical documentation review is applicable to all devices. However, it also provides that the Commission may expand the list of well-established types of devices exempt from that obligation.

Following a comprehensive consultation of the Medical Device Coordination Group ("MCDG"), the Commission expanded this list to include additional categories of class IIb implantable devices, such as feeding tubes, suture reinforcement patches, suture sleeves and suture buttons, among others.

Eligibility criteria:

The devices included in the expanded list cumulatively meet the criteria associated with the concept of well-established use, namely:

(i) a common, simple and stable design;
(ii) a well-known safety profile and the absence of documented safety concerns;
(iii) well-known clinical performance characteristics, integrated into the standard of care and with limited evolution in terms of indications or the state of the art;
(iv) a long presence on the European Union market.

II. Commission Delegated Regulation (EU) 2026/1451 of 20 March 2026

Regulation 2026/1451 amends the MDR as regards the list of implantable devices and class III devices exempt from the obligation to conduct clinical investigations.

Specifically, Article 61(6)(b) of the MDR exempts from the obligation to conduct clinical investigations those devices whose clinical evaluation is based on sufficient clinical data and is in conformity with the applicable common specifications. Following consultation with the MDCG, the Commission expanded this list to include new types of devices, such as catheters, dental implants and reusable surgical instruments, among others.

It should be noted that the exemption from the obligation to conduct clinical investigations does not relieve manufacturers from the obligation to plan, conduct and document a clinical evaluation in accordance with Article 61 of the MDR. This is an essential distinction for regulatory compliance purposes, which economic operators in the sector should bear in mind.

Both regulations represent a significant step in the consolidation of the EU medical devices regulatory framework, by expanding the exemption lists under the MDR on the basis of well-established use criteria. The revision follows a comprehensive consultation of the MDCG and reflects the experience accumulated since the MDR entered into full application in May 2021. It should be noted that both instruments enter into force on the 19 July 2026 and are binding in their entirety and directly applicable in all Member States.

For manufacturers of the covered devices, the amendments entail a reduction in procedural requirements within the conformity assessment procedure (Delegated Regulation (EU) 2026/1359) and the clinical evaluation process (Delegated Regulation (EU) 2026/1451), without, however, eliminating the substantive obligations relating to safety and clinical performance arising from the MDR.

Both delegated regulations reflect the phased and evidence-based approach that has characterised the implementation of the MDR, contributing to greater regulatory predictability in the sector. Manufacturers and other economic operators covered by these regulations should verify whether their products are eligible for the new exemptions and, if so, adapt their internal conformity assessment and clinical evaluation procedures accordingly.

Thinking about tomorrow? Let's talk today.

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