MFA Legal & Tech

MDR: EU introduces a more flexible regulatory framework for well-established technologies

Amendment to the table in Regulation (EU) 2017/745 on medical devices (MDR)

On 29 June, the **European Commission** published two Delegated Regulations amending the framework established by Regulation (EU) 2017/745 on medical devices (MDR): **Delegated Regulation (EU) 2026/1359** and **Delegated Regulation (EU) 2026/1451**.

Both instruments reflect the recognition that certain technologies with a well-established use justify a more proportionate regulatory treatment, without undermining safety and clinical performance requirements.

The underlying rationale is straightforward:

↓

medical devices with a well-established use, understood as devices with a common, simple and stable design, well-known safety profile and no history of significant issues, well-characterised clinical performance and a long track record on the Union market, should benefit from a more proportionate regulatory regime.

Delegated Regulation (EU) 2026/1359 amends **Article 52(4) MDR**, expanding the list of class IIb implantable devices exempted from the obligation for notified bodies to assess the technical documentation for all devices of the type. Among others, the exemption will now cover feeding tubes, suture pledgets, suture sleeves, bone wax, bone fillers, spinal posterior fixations, dental implants and orthodontic devices

MFA Legal & Tech

Delegated Regulation (EU) 2026/1451, in turn, amends **Article 61(6)(b) MDR**, broadening the list of implantable devices and class III devices that are exempted from the requirement to conduct clinical investigations, provided that sufficient clinical data are available.

Examples include

- cranial perforators and blades;
- catheters coated;
- catheters coated with anticoagulants
- blood bags incorporating anticoagulants;
- dental veneers;
- reusable surgical instruments
- springs for skull enlargement;
- guidewires;
- and other connection and fixation tools.

The most immediate benefit of these two Delegated Regulations lies in the reduction of the time and cost associated with bringing these technologies to market, avoiding duplication of assessment efforts for products whose safety and clinical performance have already been extensively demonstrated. They also enable regulators and notified bodies to focus their resources on genuinely innovative devices, thereby strengthening the protection of public health precisely where it is most needed.

MFA Legal & Tech

Both Delegated Regulations are directly applicable in all Member States of the European Union and will enter into force on **19 July 2026**.

MFA Legal & Tech