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# COMMISSION DELEGATED REGULATION (EU) 2026/1359

## of 20 March 2026

## amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of class IIb implantable devices exempted from the obligation to perform an assessment of the technical documentation for every device

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([1]), and in particular Article 52(5) thereof,

Whereas:

(1) In accordance with Regulation (EU) 2017/745, the Commission may amend the list of types of class IIb implantable devices which are exempted from the obligation to perform an assessment of the technical documentation for every device in the course of the conformity assessment procedure.

(2) Experience with the application of Regulation (EU) 2017/745 has demonstrated that in addition to the types of class IIb implantable devices listed in Article 52(4), second subparagraph, of Regulation (EU) 2017/745, several other types of class IIb implantable devices also meet the criteria to be considered well-established since they have common, simple and stable design; they have well-known safety and they have not been associated with safety issues in the past; they have well-known clinical performance characteristics and they are standard of care devices with little evolution in indications and the state of the art; and they have a long history on the Union market.

(3) The list of types of class IIb implantable devices set out in Article 52(4) should therefore be amended to include other well-established technologies.

(4) In order to determine which well-established technologies are to be added to the list of implantable devices set out in Article 52(4) of Regulation (EU) 2017/745, the Commission undertook a wide consultation of the Medical Device Coordination Group.

(5) Regulation (EU) 2017/745 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 52(4) of Regulation (EU) 2017/745, the second subparagraph is replaced by the following:

'However, for class IIb implantable devices, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device, except for the following class IIb implantable devices:

(a) sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, connectors,

([1]) OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.

(b) cannulas, catheters, feeding tubes, suture pledgets, suture sleeves, suture buttons, gastrostomy buttons, bone wax, bone fillers, bone substitutes, stem centralisers, diaphyseal obturators, radiography markers, fiber ligatures, transpalatal distractors, nails, anchors, spinal posterior fixations, textile braids, dental implants, orthodontic devices, dental barriers, suspensory fixations and cinches.'.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 March 2026.

*For the Commission*
*The President*
Ursula VON DER LEYEN