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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	20 March 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2026) 1809 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... 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

Delegations will find attached document C(2026) 1809 final.

Encl.: C(2026) 1809 final

EUROPEAN
COMMISSION

Brussels, 20.3.2026
C(2026) 1809 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 20.3.2026

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Well established technologies (WET) are relatively simple devices, having common and stable designs with little evolution, well-known safety and clinical performance characteristics and a long history on the market. Criteria for identifying WET have been set in Medical Device Coordination Group guidance (MDCG 2020-6).

Article 52(4) of Regulation (EU) 2017/745 lists a number of technologies which, by virtue of being WET, may benefit from a simplified approach, in this case the exemption from the requirement of the assessment of technical documentation for each device, in the course of the conformity assessment procedure. Furthermore, Article 52(5) empowers the Commission to expand the list of WET to devices similar to those listed.

Based on the experience gained so far with the MDR, this delegated act aims at expanding the lists of type of class IIb implantable devices in Article 52(4) of Regulation (EU) 2017/745 to exempt them from the requirement for the obligation to perform an assessment of the technical documentation for every device.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The list of WET devices included in this Delegated Act has been developed in 2025 through a wide consultation of the stakeholders having observer status of the MDCG Clinical Investigation and Evaluation Performance Studies and Evaluation Working Group and of the Borderline and Classification Working Group, and of the Competent Authorities members of the MDCG itself.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal act aims at expanding the list of type of class IIb implantable devices in Article 52(4) of Regulation (EU) 2017/745 which are exempt from the requirement of a technical documentation for each device, in the course of the conformity assessment procedure.

COMMISSION DELEGATED REGULATION (EU) …/...

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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 1123/2009 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:

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

‘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,

(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, 20.3.2026

For the Commission
The President
Ursula VON DER LEYEN