Council of the European Union

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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) 1798 final
Subject:	COMMISSION DELEGATED REGULATION (EU) â€¦/... amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of implantable devices and class III devices exempted from the obligation to perform clinical investigations

Delegations will find attached document C(2026) 1798 final.

Encl.: C(2026) 1798 final

EUROPEAN
COMMISSION

Brussels, 20.3.2026
C(2026) 1798 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 implantable devices and class III devices exempted from the obligation to perform clinical investigations

(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 61(6)(b) 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 to perform clinical investigations. Furthermore, Article 61(8) 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 devices in Article 61(6)(b) of Regulation (EU) 2017/745 to exempt them from the requirement to perform clinical investigations.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The list of WET devices included 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 implantable and class III devices in Article 61(6)(b) of Regulation (EU) 2017/745 which are exempt from the requirement to perform clinical investigations.

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(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 61(8) thereof,

Whereas:

(1) In accordance with Regulation (EU) 2017/745, the Commission may amend the list of implantable devices and class III devices which are exempted from the obligation to perform clinical investigations.

(2) Experience with the application of Regulation (EU) 2017/745 has demonstrated that in addition to the types of implantable devices and class III devices listed in Article 61(6), point (b), of Regulation (EU) 2017/745, several other types of implantable devices and class III 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 implantable devices and class III devices set out in Article 61(6), point (b), 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 and class III devices set out in Article 61(6), point (b), of Regulation (EU) 2017/745, the Commission undertook a wide consultation of the Medical Device Coordination Group.

(5) Although manufacturers are exempted from the obligation to perform clinical investigations for the types of implantable devices and class III devices listed in this Regulation, they are nonetheless required to plan, conduct and document a clinical evaluation in accordance with Article 61 of Regulation (EU) 2017/745 for those devices.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

In Article 61(6) of Regulation (EU) 2017/745, point (b) is replaced by the following:

‘(b) for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available and that are one of the following:

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

(b) cranial perforators, cranio-blades, catheter passers, patties and strips, magnets for implantable pulse generators, port plugs, stylets and stylet guides, needles, needle holders, forceps, cannulas, atrioseptostomy balloon catheters, catheters coated with anticoagulants, blood bags incorporating anticoagulants, port catheters, introducers, dilators, ventricular drains, feeding tubes, suture pledgets, suture sleeves, suture buttons, gastrostomy buttons, bone tacks, bone wax, bone fillers, bone substitutes, stem centralisers, diaphyseal obturators, radiography markers, fiber ligatures, tubal extraluminal ligation devices, transpalatal distractors, nails, anchors, spinal posterior fixations, textile braids, dental implants, orthodontic devices, dental barriers, dental veneers, suspensory fixations and cinches, reusable surgical instruments, springs for skull enlargement, guidewires, pressure wires, pacing wires and leads, snares, lead caps, fixation and connector tools, endovascular embolisation coils, embolisation particles, cables, shunts and internal defibrillation paddles.’.

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