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COMMISSION DECISION (EU) 2025/2371

of 26 November 2025

on the notice regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the European Database on Medical Devices referred to in Article 34(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council

(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 34(3) thereof,

Whereas:

(1) According to Article 33(1) of Regulation (EU) 2017/745 and Article 30(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council ([2]), the Commission is to set up, maintain and manage the European Database on Medical Devices (Eudamed). Eudamed is to include the electronic systems listed in Article 33(2) of Regulation (EU) 2017/745 and Article 30(2) of Regulation (EU) 2017/746.

(2) On 15 December 2022, the Commission published the latest consolidated version of the functional specifications of Eudamed (version 7.2) ([3]), which it had drawn up in collaboration with the Medical Device Coordination Group ('MDCG') in accordance with Article 34(1) of Regulation (EU) 2017/745.

(3) In accordance with Article 34(2) of Regulation (EU) 2017/745, the Commission requested an independent audit on the Eudamed electronic systems for which the development has been completed. Such electronic systems are the electronic system on registration of economic operators ('Actors'), the UDI database and the electronic system for registration of devices ('UDI and devices'), the electronic system on notified bodies and certificates ('Notified bodies and certificates'), and the electronic system on market surveillance ('Market surveillance').

(4) On the basis of the independent audit report of 18 June 2025 on the 'Actors', 'UDI and devices', 'Notified bodies and certificates', and 'Market surveillance' electronic systems, the Commission has verified that such electronic systems are functional and meet the relevant functional specifications drawn up pursuant to Article 34(1) of Regulation (EU) 2017/745.

(5) As set out in Article 123(3), points (d) to (ec), of Regulation (EU) 2017/745 and Article 113(3), points (f) to (fd) of Regulation (EU) 2017/746, the transition periods for the obligations and requirements that relate to any of the electronic systems referred to in those Regulations are to start as from the date of publication of this Decision on the notice as referred to in Article 34(3) of Regulation (EU) 2017/745, informing that the relevant electronic systems are functional and meet the functional specifications.

(6) In order to ensure legal certainty and a clear timeline for the mandatory use of the electronic systems declared functional, this Decision should enter into force on the day of its publication.

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

([2]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

([3]) https://health.ec.europa.eu/system/files/2022-12/md_eudamed_fs_v7_2_en.pdf.

HAS ADOPTED THIS DECISION:

Article 1

It is hereby confirmed that the following electronic systems included in the European Database on Medical Devices (Eudamed) have achieved functionality and meet the functional specifications, as referred to in Article 34(2) of Regulation (EU) 2017/745:

(a) the electronic system on registration of economic operators referred to in Article 30 of Regulation (EU) 2017/745 and Article 27 of Regulation (EU) 2017/746;

(b) the UDI database and the electronic system for registration of devices referred to in Articles 28 and 29 of Regulation (EU) 2017/745 and Articles 25 and 26 of Regulation (EU) 2017/746;

(c) the electronic system on notified bodies and certificates referred to in Article 57 of Regulation (EU) 2017/745 and Article 52 of Regulation (EU) 2017/746;

(d) the electronic system on market surveillance referred to in Article 100 of Regulation (EU) 2017/745 and Article 95 of Regulation (EU) 2017/746.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 26 November 2025.

For the Commission
The President
Ursula VON DER LEYEN