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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2526

of 16 December 2025

amending Implementing Regulation (EU) 2023/2713 to correct the designation of an EU reference laboratory and to designate European Union reference laboratories for *in vitro* diagnostic medical devices intended for detection or quantification of markers of parasite infection and detection of blood grouping markers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/746 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 ([1]), and in particular Article 100(1) thereof,

Whereas:

(1) The designation of the consortium managed by Servicio Madrileño de Salud (SERMAS) as an EU reference laboratory by Commission Implementing Regulation (EU) 2023/2713 ([2]) should be corrected to include the foundations associated with the members of the consortium, to facilitate the administration of the Union contribution granted to this EU reference laboratory in accordance with Article 100(6) of Regulation (EU) 2017/746.

(2) In accordance with Article 100(1) of Regulation (EU) 2017/746, in February 2025 the Commission launched a call for applications for EU reference laboratories in various scopes of designation as referred to in Article 1(1) of Commission Implementing Regulation (EU) 2022/944 ([3]). The first wave of the call was for four scopes of designation with a deadline for application to the Commission of 6 June 2025.

(3) In response to the call of February 2025, applications for designation were submitted by Member States and evaluated by a selection board set up by the Commission services.

(4) The selection board took into account the criteria for EU reference laboratories laid down in Article 100(4) of Regulation (EU) 2017/746 as well as Articles 1 to 9 of Implementing Regulation (EU) 2022/944.

(5) When an EU reference laboratory is designated, according to Article 48(5) of Regulation (EU) 2017/746, and Sections 4.11 and 4.12 of Annex IX, as well as Section 5.4 of Annex X, and Section 5.1 of Annex XI, to Regulation (EU) 2017/746, class D devices have to undergo performance verification and batch testing by the EU reference laboratory in accordance with Article 100(2), points (a) and (b), respectively, of that Regulation. Therefore, to ensure sufficient availability of EU reference laboratory services, the selection board also took into account the collective capacity of the candidate laboratories for performance verification and batch testing.

(6) Following the completion of the selection procedure, the successful laboratories should be designated as the EU reference laboratories, specifying their scope of designation.

([1]) OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.

([2]) Commission Implementing Regulation (EU) 2023/2713 of 5 December 2023 designating European Union reference laboratories in the field of *in vitro* diagnostic medical devices (OJ L, 2023/2713, 6.12.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2713/oj).

([3]) Commission Implementing Regulation (EU) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of *in vitro* diagnostic medical devices (OJ L 164, 20.6.2022, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2022/944/oj).

(7) To ensure legal certainty and predictability of conformity assessment procedures, the newly designated EU reference laboratories should only perform the task set out in Article 100(2), point (a), of Regulation (EU) 2017/746 in respect of devices for which the formal application for conformity assessment is lodged after the designation of the EU reference laboratories applies for the purpose of the tasks set out in Article 100(2) of that Regulation.

(8) Implementing Regulation (EU) 2023/2713 should therefore be amended and corrected accordingly.

(9) Article 100(5) of Regulation (EU) 2017/746 provides that the EU reference laboratories are to form a network in order to coordinate and harmonise their working methods as regards testing and assessment, which is necessary for performing the tasks set out in Article 100(2) of that Regulation. Moreover, manufacturers and notified bodies need to adapt their existing processes for conformity assessment of devices as a consequence of the designation of new EU reference laboratories and their involvement in conformity assessment. To allow the newly designated EU reference laboratories sufficient time to join the network of already designated EU reference laboratories, and to coordinate and harmonise their working methods, and for manufacturers and notified bodies to adapt their processes, the application of the designation of the newly designated EU reference laboratories for the purposes of the tasks referred to in Article 100(2) of Regulation (EU) 2017/746 should be deferred until a later date,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2023/2713 is amended in accordance with the Annex to this Regulation.

Article 2

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

2. For the purpose of the tasks referred to in Article 100(2) of Regulation (EU) 2017/746, point 3 of the Annex to this Regulation shall apply from 1 May 2026.

3. Without prejudice to paragraph 2 of this Article, the EU reference laboratories designated in point 3 of the Annex to this Regulation shall carry out the task referred to in Article 100(2), point (a), of Regulation (EU) 2017/746, only for devices for which manufacturers or authorised representatives lodge formal applications for conformity assessment with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII to Regulation (EU) 2017/746 from 1 May 2026.

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

Done at Brussels, 16 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2023/2713 is amended as follows:

(1) point 2(a) is replaced by the following:

'(a) Consortium managed by:
Servicio Madrileño de Salud (SERMAS), Paseo de la Castellana 280, 28046, Madrid, Spain
and composed of

Hospital General Universitario Gregorio Marañón and Fundación para la Investigación Biomédica del Hospital Gregorio Marañón, C/Doctor Esquerdo n°46, 28007, Madrid, Spain,

Hospital Universitario la Paz, Paseo de la Castellana 261, 28046, Madrid, Spain, and

Hospital Universitario Ramón y Cajal, Carretera de Colmenar Viejo Km 9,100, 28034, Madrid, Spain;';

(2) point 3(a) is replaced by the following:

'(a) Consortium managed by:
Servicio Madrileño de Salud (SERMAS), Paseo de la Castellana 280, 28046, Madrid, Spain
and composed of

Hospital General Universitario Gregorio Marañón and Fundación para la Investigación Biomédica del Hospital Gregorio Marañón, C/Doctor Esquerdo n°46, 28007, Madrid, Spain,

Hospital Universitario la Paz, Paseo de la Castellana 261, 28046, Madrid, Spain, and

Hospital Universitario Ramón y Cajal, Carretera de Colmenar Viejo Km 9,100, 28034, Madrid, Spain;';

(3) the following points 5 and 6 are added:

'5. EU reference laboratories for devices intended for detection or quantification of markers of parasite infection:

(a) Instituto de Salud Carlos III, Carretera de Majadahonda – Pozuelo, Km. 2,200, 28220, Majadahonda, Madrid, Spain;

(b) Consulting Químico Sanitario SLU, Calle Marie Curie 7, 28521, Rivas-Vaciamadrid, Madrid, Spain.

6. EU reference laboratories for devices intended for detection of blood grouping markers:

(a) EU Referenzlabor für In-vitro-Diagnostika am Paul-Ehrlich-Institut, Paul-Ehrlich-Straße 51–59, 63225, Langen, Germany;

(b) Consulting Químico Sanitario SLU, Calle Marie Curie 7, 28521, Rivas-Vaciamadrid, Madrid, Spain;

(c) RISE Research Institutes of Sweden AB, Brinellgatan 4, 504 62, Borås, Sweden.'.