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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2713

of 5 December 2023

designating European Union reference laboratories in the field of *in vitro* diagnostic medical devices

(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) In accordance with Article 100(1) of Regulation (EU) 2017/746, in July 2022 the Commission launched a call for applications for EU reference laboratories in eight scopes of designation as referred to in Article 1(1) of Commission Implementing Regulation (EU) 2022/944 ([2]).

(2) In response to the call of July 2022, applications for designation were submitted by Member States by 31 March 2023 and evaluated by a selection board set up by the Commission services.

(3) 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.

(4) 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.

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

(6) 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 EU reference laboratories and their involvement in conformity assessment. To allow the newly designated EU reference laboratories sufficient time to form a network and coordinate and harmonise their working methods, and manufacturers and notified bodies to adapt their processes, the application of the designation of the 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.

([1]) 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).

([2]) 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).

(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,

HAS ADOPTED THIS REGULATION:

Article 1

The laboratories listed in the Annex are designated as EU reference laboratories for the specific devices or a category or group of devices, or for specific hazards related to a category or group of devices, as specified in that Annex.

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, this Regulation shall apply from 1 October 2024.

3. Without prejudice to paragraph 2 of this Article, EU reference laboratories 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 October 2024.

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

Done at Brussels, 5 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

EU reference laboratories designated in accordance with Article 1

1. EU reference laboratories for devices intended for detection or quantification of markers of hepatitis or retrovirus infection:

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

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

2. EU reference laboratories for devices intended for detection or quantification of markers of herpesvirus infection:

(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, 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;

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

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

3. EU reference laboratories for devices intended for detection or quantification of markers of infection with bacterial agents:

(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, 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;

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

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

4. EU reference laboratories for devices intended for detection or quantification of markers of respiratory virus infection:

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

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