EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE.DDG1.D.3/OT/

Subject: Call for applications for designation of EU reference laboratories in the field of *in vitro* diagnostic medical devices

Your Excellency,

I am pleased to inform you that, with this letter, the Directorate General for Health and Food Safety is formally launching a call for applications for designation of EU reference laboratories (EURLs) in the field of *in vitro* diagnostic medical devices, under Regulation (EU) 2017/746. The call will be run in two waves and covers various categories of devices of risk class D.

I would be grateful if you could forward the attached documentation to all relevant authorities in your country. I would like to draw your attention to the fact that applications must be submitted by the Member States.

Let me stress that the requirements in the call must be strictly complied with, including the deadlines for submission of applications.

I look forward to the possible submission of applications for candidate EURLs by your country.

Please contact the following e-mail addresses: SANTE-IVD@ec.europa.eu; SANTE-MED-DEV@ec.europa.eu for further information (subject: Call for applications for designation of EURLs). For technical assistance during the submission of applications, please send an email to: JRC-MEDICAL-DEVICES@ec.europa.eu.

For background, this is the second call for EURLs under Regulation (EU) 2017/746. The first call was carried out in 2022, following which five EURLs were designated covering the following categories of class D devices: detection or quantification of markers of hepatitis and retroviruses, herpesviruses, bacterial agents and respiratory viruses that cause life-threatening diseases. More information can be found here: https://health.ec.europa.eu/medical-devices-vitro-diagnostics/eu-reference-laboratories-eurls_en

Yours faithfully,

Sandra GALLINA

By email to:

Permanent Representations of all EU Member States
Missions of Norway, Iceland, Liechtenstein and Turkey to the EU

Copy to:

Members and observer countries of the Medical Device Coordination Group

Enclosure: Call for applications for designation of EU reference laboratories in the field of *in vitro* diagnostic medical devices, with 12 annexes