

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

Grange SANTE.F5 MG/dht

Subject: Invitation to a national expert to take part in the joint re-assessment of

DNV Medcert GmbH (NB 0482) to be carried out in Germany from 25 to

29 November 2024 pursuant to Regulation (EU) 2017/745

Ref.: DG(SANTE) 2024-7954

Your Excellency,

I would like to invite Ms Kristina Kübar of the Estonian Health Board to participate in the planned assessment of DNV Medcert GmbH (NB 0482) to be carried out under the medical devices Regulation (Regulation (EU) 2017/745) from 25 to 29 November 2024.

In addition to Ms Kübar, the assessment will include two experts from the Directorate General for Health and Food Safety. The team coordinator will be Mr Manuel Gimenez (telephone: +353 46 9061 883, email: <u>SANTE-F-MEDICAL-DEVICES@ec.europa.eu</u>).

This invitation is being sent to you as a matter of protocol. No action is needed on your part. A note explaining the procedures applicable to the national expert taking part in this assessment and the necessary documents to confirm her participation are attached. These should be filled in by the national expert and returned directly to SANTE-IRL-MISSIONS@ec.europa.eu.

Mr Gimenez is available to provide any additional information concerning the assessment. The assessment reference DG(SANTE) 2024-7954 should be used in all future correspondence.

I have the honour to be,

Yours faithfully,

(e-signed)

María Pilar Aguar Fernández

c.c. National Expert, kristina.kubar@terviseamet.ee

H.E. Ambassador Permanent Representation of Estonia to the EU Rue Guimard 11-13 B-1040 Brussels Belgium