EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Devices

Brussels
SANTE.D.3/MCO(2023)12013708

Subject: **Study supporting the monitoring of availability of medical devices on the EU market** (HADEA/2021/P3/03 ([1]))

Dear Sir, / Dear Madam,

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned a "**Study supporting the monitoring of availability of medical devices on the EU market**". The study started in December 2022 and will be running for 36 months (December 2025).

The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting.

The **general objective** of the study is **to monitor and analyse the availability of medical devices on the EU market** in the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. To that purpose, relevant stakeholders will be mapped and consulted, and information needs as well as data sources will be set. The study team will also design and establish a dashboard to gather the data retrieved and, based on feedback received, identify obstacles that could affect availability of devices and/or impair the conformity assessment process, pointing to potential solutions.

The terms of reference for the study require therefore the contractor to **approach stakeholders for several consultation activities**, including surveys and interviews. Given the importance of the study to gather concrete data essential to monitor implementation of the Regulations and provide the Medical Device Coordination Group (MDCG) with the needed outcome ([2]), we **kindly invite you to assist the study team** if you are requested to **provide input, complete a survey and/or participate in an interview**. We really value your contribution to this study.

([1]) Specific contract No 2021 P3 03 implementing framework contract No SANTE/2021/OP/0002

([2]) To be noted that MDCG 2022-14 *MDCG Position Paper - Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs* indicates that MDCG counts also on the full commitment of all actors involved, including notified bodies and industry, to provide the data necessary for the monitoring of the market by the MDCG.

The study team is required to act in full compliance with EU competition law, they will keep any specific information (raw data) collected at individual company level **strictly confidential** and under no circumstances to disclose individualised information. The study team has committed to take all necessary security steps to ensure that the data is handled with the utmost care and protection. Only **aggregated survey outcomes will be published and included in the analysis reports**.

Should you have any questions, please do not hesitate to contact SANTE-MED-DEV@ec.europa.eu, and/or the study's Project Manager Friederike Windisch (Friederike.Windisch@goeg.at).

Yours faithfully,

(Electronically signed)

Flora Giorgio
Head of Unit