EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Devices

Brussels
SANTE.D.3/ SANTE.D.3(2025)12460946

Subject: **Analyses on markets of medical devices and of medicinal products – MedPro II** (HADEA/2024/OP/0029)[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 on "**Analyses on markets of medical devices and of medicinal products – MedPro II**".

The study, which started on 18 September 2025 and will end on 17 March 2026, has been contracted to a consortium led by Technopolis. Under Sub-Task 1.4, which is led by the Austrian National Public Health Institute (Gesundheit Österreich Beratungs GmbH/GÖ B) and supported by RAND Europe and Milieu Consulting SRL, the study team will conduct an analysis on impact of changes on requirements for the reprocessing of devices.

The main objective of this analysis is **to investigate the reprocessing of single-use devices (SUDs)** conducted in accordance with Article 17 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation / MDR), and compare costs, timelines and procedures with those for the reuse of surgical instruments (e.g. cleaning, disinfection, sterilization, maintenance and functional testing). The study will feed in the discussions related to the forthcoming review of the MDR, in particular on the simplification of requirements applicable to the reprocessing of single-use devices.

To conduct the study appropriately, the study team will **approach stakeholders (e.g., industry representatives, notified bodies, healthcare providers) for several consultation activities**, including interviews and a survey. This consultation is a key source of information for the assignment, and we **kindly invite you to support the study team** by **providing input**. Thank you in advance for your valued cooperation.

[1] Specific contract No HADEA/2025/SC/0038 implementing framework contract No SANTE/2024/OP/0029

Acting in full compliance with EU competition law, and within its limits, the study team will treat all specific information (raw data) collected at the individual level strictly confidential and under no circumstances will individual information be disclosed. The study team will ensure that the data is handled with the utmost care and protection. Only aggregated survey outcomes will be published and included in the final reports.

Should you have any questions, please do not hesitate to contact SANTE-MED-DEV@ec.europa.eu, and/or the study team (medical.devices@goeg.at).

Yours faithfully,

(Electronically signed)

Flora Giorgio
Head of Unit