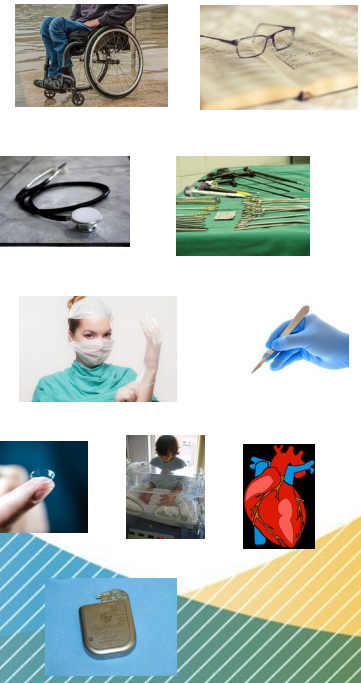
PPRI MD

PPRI MD Webinar

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market **(HaDEA/2021/P3/04)**



→ Single-use devices and reprocessing

23 May 2023, 11-12am

Friederike Windisch, Nina Zimmermann

Online via Zoom

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

S&P Global Commodity Insights

Gesundheit Österreich GmbH

Definitions

Single-use device

A device that is intended to be used on one individual during a single procedure.

Source: MDR (EU) 2017/745

Reprocessing

The process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device.

Source: MDR (EU) 2017/745

Reprocessor

The health institution and the external reprocessor reprocessing single-use devices.

Source: Common specifications 2020

Key facts

Commissioned by:

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - **HADEA/2021/P3/04**

Consortium:

- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute
- **Project partners:** Areté, Agra CEAS Consulting IHS Markit (now part of S&P Global), Civic Consulting

Project manager:

Ms Friederike Windisch, Ms Nina Zimmermann (deputy)

Key contacts DG SANTE/HaDEA:

Ms Erica Poot (HaDEA), Mr Gabriele Calligaro (DG SANTE)

Duration:

15 December 2022 – 14 February 2024 (14 months)

Study objectives

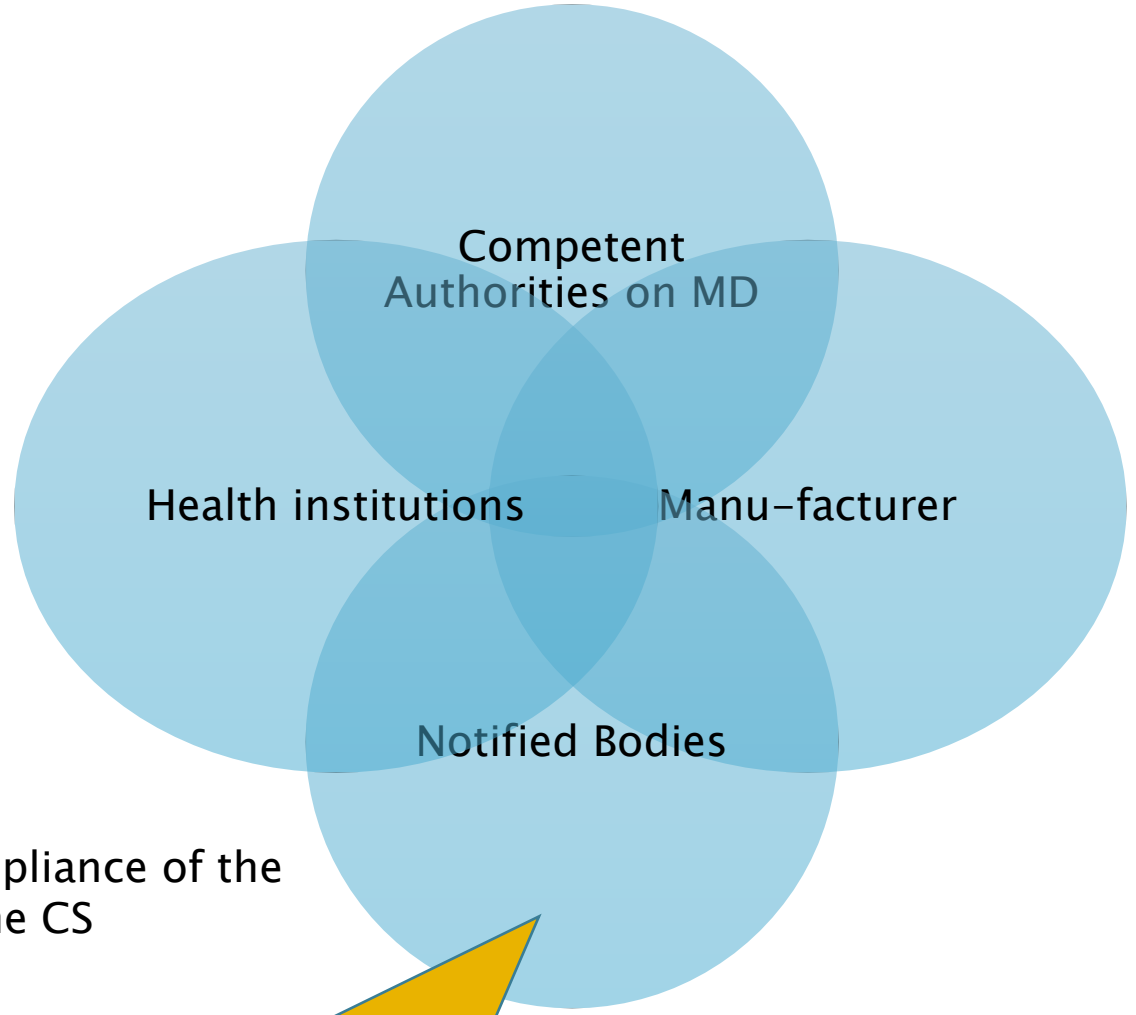
General objective

To **evaluate how the provisions established in Article 17 of MDR have been implemented by EU Member States and how such provisions operate.** For this purpose, the **current market situation** for **reprocessing and reuse of single-use MD in Europe** (EU MS and other countries) will be presented.

Five specific objectives (SO):

- **SO1:** To **quantify the reprocessors** operating in each Member State, to identify the types of single-use devices reprocessed and to estimate the **quantities reprocessed** per year per each type
- **SO2:** To **quantify the certificates** issued by Notified Bodies to confirm the compliance to the CS;
- **SO3:** To **develop a dashboard**, including relevant indicators for all the Member States permitting the reprocessing at national level, consisting of tables, graphs and other tools useful to show the results of the collected data and information in a stratified manner
- **SO4:** To identify and analyze **challenges and obstacles** (e.g., national restrictions/prohibitions, Notified Body availability or capacity, regulatory requirements and related costs, etc.) that could affect the reprocessing of single-use devices
- **SO5:** To present the outcomes of the analysis in a report with user-friendly layout, including infographics and possible **solutions/recommendations** to remove obstacles and challenges also considering the dissemination among stakeholders and the public.

Key stakeholders



reprocessing and reusing single-use devices

that reprocess single-use devices

certifying the compliance of the reprocessing to the CS

Note: Only NB designated under MDR!

Scope of the study

1. Product scope:

The collection of data foreseen in this study is aimed **to cover single-use devices only**.

a) Product types: CE marked medical devices (MD) intended for single use

Note: Reprocessing can be carried out on medical devices, accessories for medical devices or Annex XVI products (cf. Article 1(4) of MDR)

b) **Market status**: devices available on the EU market

c) **Risk classes**: devices belonging to all risk classes (if reprocessed)

2. Geographic scope:

27 EU countries plus Iceland, Liechtenstein and Norway (**30 countries** in total)

3. Time scope:

15 December 2022 – 14 February 2024 (14 months)

Consultation activities

Period: May 2023 - November 2023

Targeted surveys

- Notified bodies
- Manufacturer
- Competent Authorities
- Health institutions

Follow-up interviews

Development of a dashboard

Synopsis report and final dashboard
(probably not publicly available)

Thank you very much for your attention!

Friederike Windisch
M: +43 676 848 191 – 110
friederike.windisch@goeg.at
Projektleiterin

Nina Zimmermann
M: +43 676 848 191 - 102
nina.zimmermann@goeg.at
Stv. Projektleiterin

Please contact the study team in case of questions, suggestions or comments!

Contact e-mail address: medical.devices@goeg.at