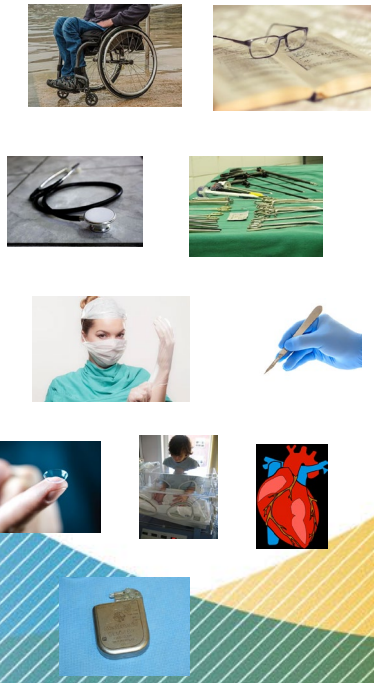
Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market

EU4Health Programme



53rd CAMD plenary meeting

Friederike Windisch, Austrian National Public Health Institute

19 September 2023

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

S&P Global Commodity Insights

Gesundheit Österreich GmbH

Article 17 of Regulation (EU) 2017/745 on medical devices → **Single-use devices and their reprocessing**

Article 17

Single-use devices and their reprocessing

1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.

3. By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;

(b) the reprocessing is performed in accordance with CS detailing the requirements concerning:

— risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,

— the validation of procedures for the entire process, including cleaning steps,

— the product release and performance testing,

— the quality management system,

— the reporting of incidents involving devices that have been reprocessed, and

— the traceability of reprocessed devices.

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

4. Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.

5. The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.

6. Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2020 in accordance with Directive 93/42/EEC, may be reprocessed.

7. Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.

8. The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Study on the implementation of Article 17 of Regulation (EU) 2017/745 on MD on the EU market

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 - Specific contract No 2021 P3 04 implementing framework contract No SANTE/2021/OP/0002

Consortium:
- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute
- **Project partners:** Areté, S&P Global, Civic Consulting

Project manager:
Ms Friederike Windisch, Ms Nina Zimmermann (deputy)

Key contacts HaDEA/DG SANTE:
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 devices (SUDs) 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.

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)

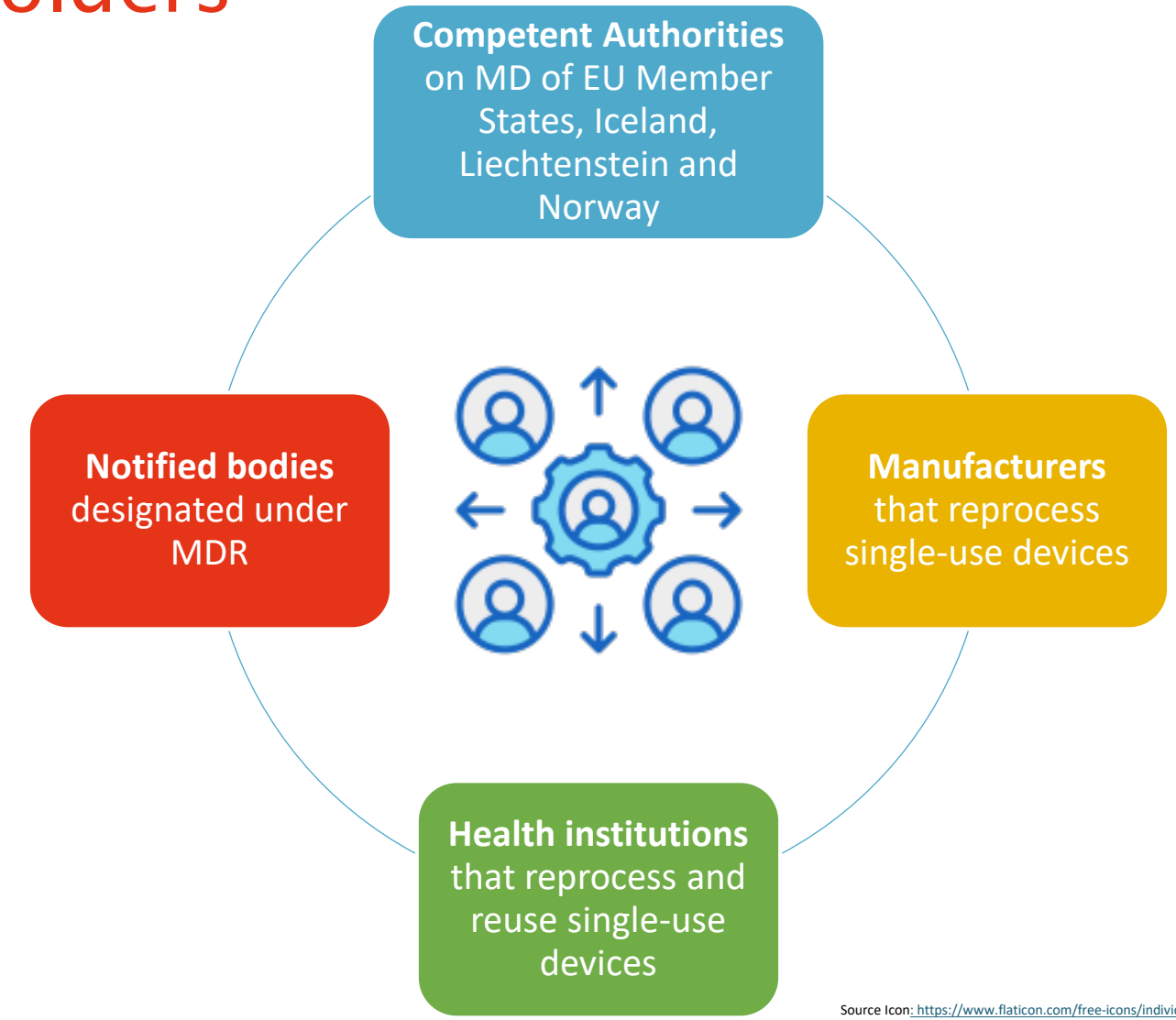
b) Market status: devices available on the EU market

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

2. **Geographic scope:** 27 EU Member States plus Iceland, Liechtenstein and Norway (**30 countries** in total)

3. **Time scope:** 14 months starting from the date of signature of the contract **(15 December 2022 – 14 February 2024)**

Key stakeholders



Source Icon: https://www.flaticon.com/free-icons/individual

Source: GÖG

Consultation activities and presentation of results

Targeted surveys

Final report
Publication planned for
February/March 2024

Follow-up interviews

State of play: targeted surveys / follow-up interviews

- **4 targeted surveys*** conducted between May and September 2023 via the platform EUSURVEY; update planned
- **23 follow-up interviews*** conducted between May and September 2023 and more planned

Many thanks for your support!

* data status: 17/09/2023

Notified Bodies (NBs)

- **Survey:**
  - Target: 38 NBs designated under MDR + *information e-mails sent to NB representatives (NBCG and Team NB) + to members of the NBO subgroup*
  - Launch: 24/05/2023
  - Response rate: 100% (38 out of 38 NBs)
  - Status: survey closed
- **Follow-up interviews:** 7

Competent Authorities (CAs) on MD

- **Survey:**
  - Target: CAs of 30 countries: 27 EU Member States (MS) + Norway, Lichtenstein, and Iceland
  - Launch: 12/06/2023
  - Response rate: 100 % (30 out of 30 countries)
  - Status: survey closed
- **Follow-up interviews:** 8

Manufacturers

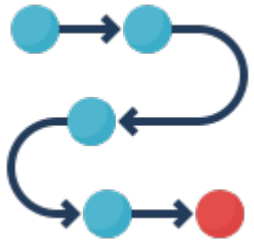
- **Survey:**
  - Target: manufacturers directly; 6 national associations + dissemination via MedTech Europe
  - Launch: 24/05/2023
  - Status: survey closed
- **Follow-up interviews:** 1

Health institutions

- **Survey:**
  - Target: 15 national associations of health institutions in the 6 EU MS where reprocessing of single-use devices allowed
  - Launch: 14/06/2023
  - Status: survey closed
- **Follow-up interviews:** 7

Update planned in November 2023

Next steps



- Data validation
- Further follow-up interviews
- Survey update in November 2023 (NBs and CAs)
- Publication of final report in February / March 2024

List of abbreviations

Abbreviation	Meaning
CAs	Competent Authorities
CAMD	Competent Authorities for Medical Devices
CS	Common Specifications
DG SANTE	Directorate-General for Health and Food Safety
EEA	European Economic Area
EU	European Union
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
MD	Medical device(s)
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)
MS	Member State(s)
NBs	Notified Bodies
NBCG-Med	Notified Bodies Coordination Group for Medical Devices
NBO	Notified Bodies Oversight
SUDs	Single-use Device(s)
ToR	Terms of Reference

Thank you very much for your attention!

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

Nina Zimmermann
M: +43 676 848 191 - 102
nina.zimmermann@goeg.at
Deputy project manager

Please contact the study team in case of questions, suggestions or comments!
medical.devices@goeg.at