NEW REGULATION ON
SINGLE-USE DEVICES

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

New Medical Device Regulation (EU) 2017/745

The new Medical Device Regulation (MDR) of the European Parliament and the Council that came into force in 2021 is directly applicable EU legislation.

However, there are some topics that are reserved for the Member States to regulate by national law.

This also applies to Article 17 of the Medical Device Regulation on Single-use devices and their reprocessing.

Single-use devices and their reprocessing

As laid down in Article 17, each Member State can decide to permit the reprocessing of single-use devices or not.

In order to harmonise procedures for the reprocessing of devices within health institutions, the European Commission has laid down common specifications in the Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 defining rules for the application of the Medical Device Regulation as regards common specifications for the reprocessing of single-use devices.

Study to evaluate the implementation of provisions

The study will be executed over 14 months, starting in December 2022.

The main objective is to evaluate how the provisions established in the MDR have been implemented in European countries and how such provisions operate.

Therefore, the current market situation for the reprocessing and reuse of single-use devices in Europe will be studied.

A mixed-methods approach will be used. Final deliverables will include a dashboard presenting indicators and a report.

Single-use vs. reprocessing

The term "*single-use*" is defined in Article 2(8) of the Medical Device Regulation and relates to a "*device that is intended to be used on one individual during a single procedure*". It requires that the product is disposed of after use and must not be used a second time. In practice, two harmonised symbols are often used to mark single-use devices.

Reprocessing allows the reuse of a product: Article 2(39) of the Medical Device Regulation defines the term "*reprocessing" as a "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*". Article 17 of the Medical Device Regulation lays down the details of reprocessing.

Project details

This study is being led by Gesundheit Österreich GmbH (Austrian National Public Health Institute), in collaboration with Agra CEAS Consulting (S&P Global), Areté and Civic Consulting. The study was commissioned by the European Commission (via the European Health and Digital Executive Agency / HaDEA).

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Gesundheit Österreich GmbH · CIVIC CONSULTING · Areté The Agri-food Intelligence Company · S&P Global Commodity Insights · European Commission

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