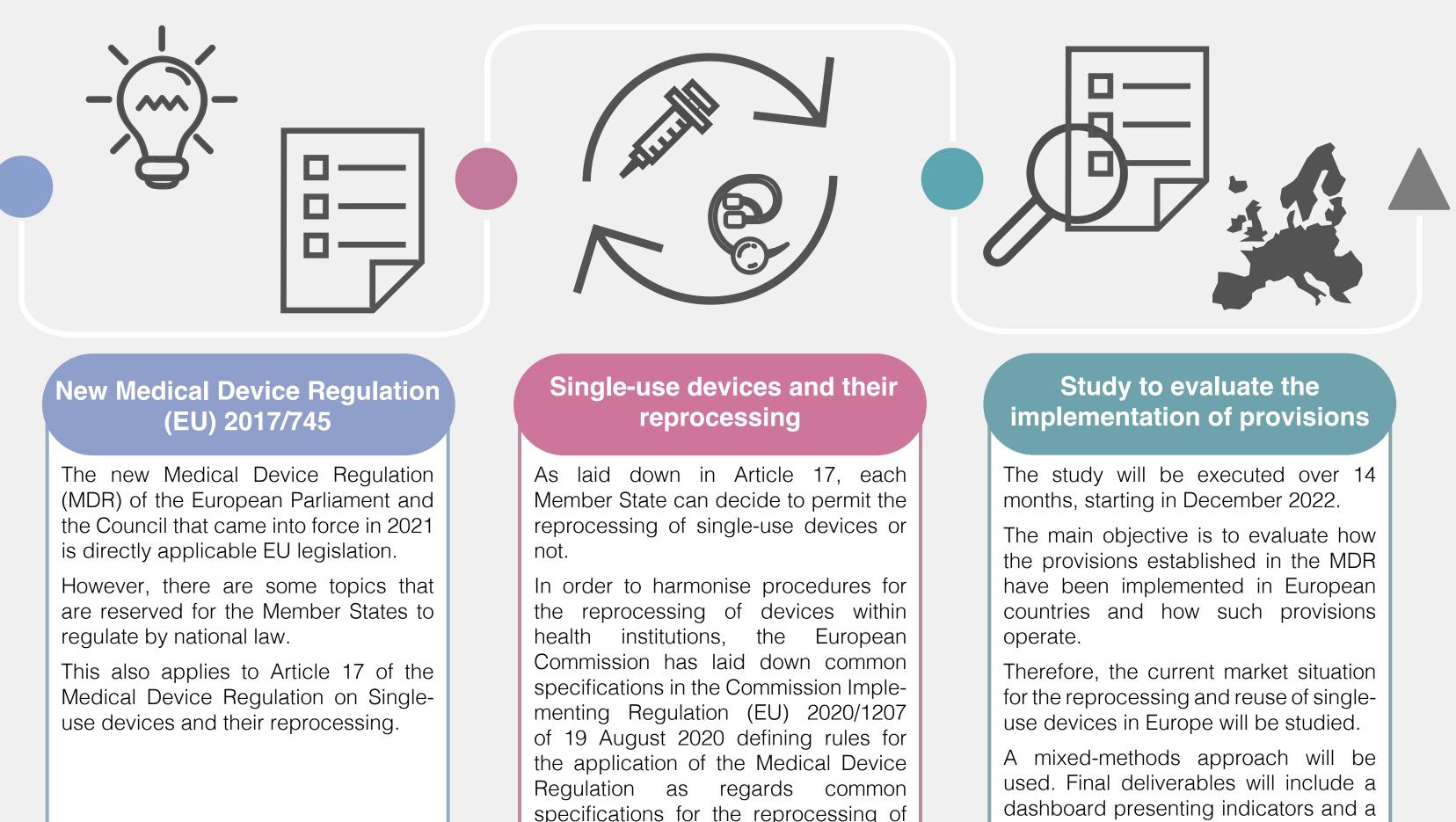
## **NEW REGULATION ON** SINGLE-USE DEVICES

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



specifications for the reprocessing of single-use devices.

CONSULTING

## Gesundheit Österreich GmbH • •

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## 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". 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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