Reprocessing of Single-Use Devices in Hospitals / Health Institutions

This fact sheet is focused on the reprocessing **by health institutions.**

Reprocessors have to assume all manufacturer obligations but 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 the EU MDR Regulation. In the latter case, Health Institutions would have to follow requirements according to the Common Specification[1] and obligations set forth by their Member State.

Under the EU MDR, reprocessing of single-use devices (SUD) may only occur where it is expressly permitted by national law. These are the main requirements for Health Institutions following the Common Specification route:

1. Determination of Suitability for Reprocessing

Not all single-use devices are suitable for reprocessing. Suitability is based on the **assessment (through a written positive opinion) of the person responsible for reprocessing. This could be the health institution itself or an external reprocessor.**

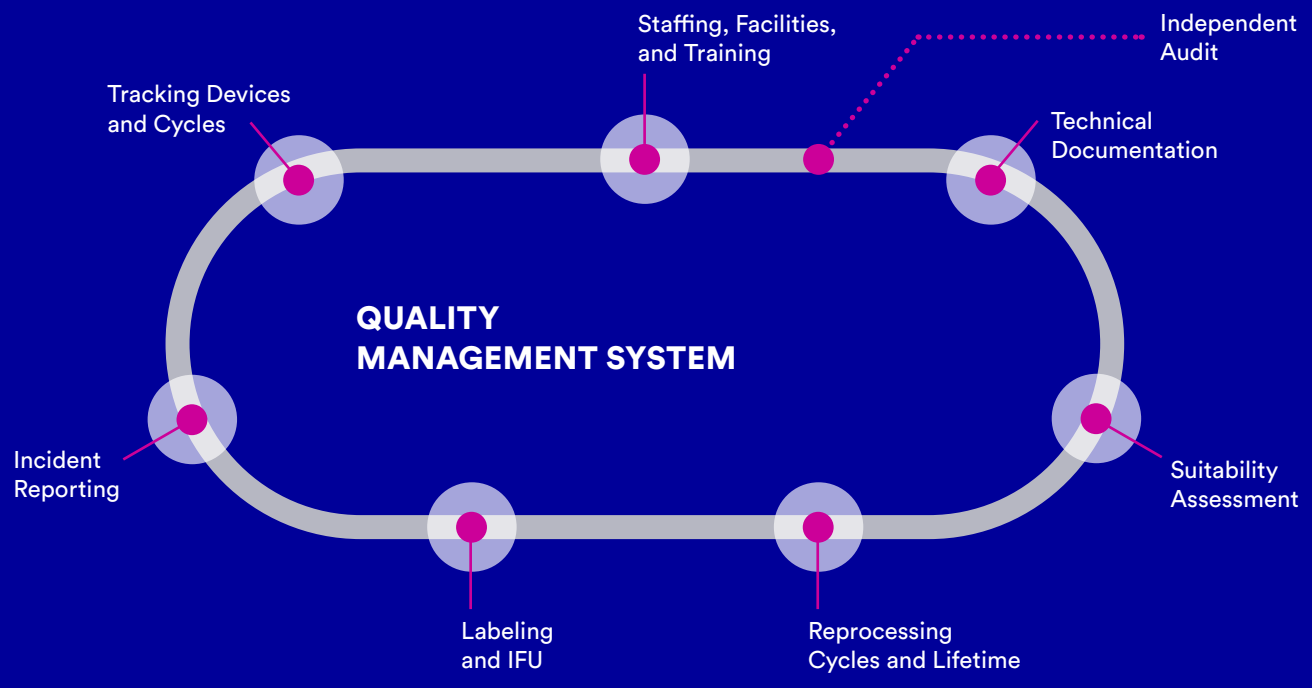
Neither the EU Medical Device Regulation (MDR)[1] nor the European Commission Common Specifications (CS)[2] include a specific list of devices prohibited from reprocessing. This will depend on the position of the Member State; although the CS provide examples of SUDs that could be considered unsuitable for reprocessing[2].

2. Contracting for Reprocessing

The health institution may act as the reprocessor of the device, or it may contract with an external reprocessor. In either case, the CS set out specific requirements for reprocessing. If an external reprocessor is used, these requirements must be established in a written contract.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

[2] Commission Implementing Regulation (EU) 2020/1207 on Re-SUD in Hospitals (CS) https://www.legislation.gov.uk/eur/2020/1207introduction



3. Quality Management System

Requirements for reprocessing are set forth in the MDR and by the Member States and must be followed by the entity performing the reprocessing, whether that is the health institution itself or the health institution in conjunction with an external reprocessor[3].

The heart of the requirements is the establishment of a Quality Management System (QMS). The Health Institution, must establish, document, implement, and maintain a QMS for the reprocessing activities in compliance with the CS and the MDR. At least one **annual independent external audit** must be conducted with the results of that audit provided to the notified body competent for the certification of the reprocessor.

[3] These rules do not apply to the sterilization of single-use devices before use.

4. Informing Patients

Neither the MDR nor the CS include mandatory patient information requirements. However, the MDR provides that (Art. 17.3):

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.

Therefore, the decision as to whether health institutions should inform patients about the use of reprocessed SUDs must be taken by Member States and included into national law.

Furthermore, the CS provide (Art. 23.6) that:

The health institution shall request its staff and, where appropriate, invite its patients to report to a contact person within the health institution any serious incident involving reprocessed single-use devices.

5. Staffing, Facilities, and Training

Health Institution Staff which reprocess SUDs must have the appropriate knowledge and professional training and be sufficient in number to ensure the quality of the reprocessing. All tasks and responsibilities related to the reprocessing must be clearly defined in writing.

6. Technical Documentation

Health Institutions which reprocess SUDs must have technical documentation on their overall reprocessing activities as well as technical documentation specific to each model of SUD as identified by its device identifier in the Unique Device Identification system (UDI-DI). This documentation needs to include the results of the determination of the reprocessing cycle and the actions to be undertaken in case one or more steps of the reprocessing cycle have not been performed.

7. Reprocessing Cycles and Lifetime

The health institution, together with any external reprocessor, should determine reprocessing cycles as well as the maximum number of cycles based on all technical information available. All assessments must be documented and validated. The reprocessing cycle should not change the intended purpose, performance, and safety of the SUD and take into account the original method of sterilization. All records regarding the steps of the reprocessing cycle must be kept for 10 years and made available to the appropriate Notified Body and, upon request, to authorities of the member state.

8. Labelling and Provision of Instructions for Use (IFU)

Name and address of the health institution and the external reprocessor (if applicable) must be on the label and in the IFU for the reprocessed SUD. The name and address of the original manufacturer of the original SUD shall no longer be on the label but should appear in the IFU for the reprocessed SUD. Single-use devices reprocessed by the Health Institutions shall bear the word ‘reprocessed’ on their label.

9. Incident Reporting

All serious incidents involving the reprocessed SUD must be reported to the relevant competent authority, and a copy sent to the manufacturer and external reprocessor. Specific requirements are identified regarding removal from service, retention periods, impact on other reprocessed devices, and yearly analysis of incidents.

10. Tracking of Devices and Reprocessing Cycles

A tracking system must be in place allowing the identification of SUDs throughout the reprocessing cycle, the lifetime of the reprocessed SUD, and, when using an external reprocessor, that the returned device is the same device sent to an external reprocessor.

Map represents ALL EU countries and does not imply approval of reprocessed single-use devices.

Sources
https://www.legislation.gov.uk/eur/2020/1207/introduction

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