PRACTICAL SHEET
REPROCESSING OF SINGLE-USE MEDICAL DEVICES

This sheet aims to offer a synthesised presentation of the requirements set by the new European regulation on medical devices for those who consider reprocessing single use medical devices. It has been updated in the light of the Implementing Regulation 2020/1207 of the European Commission, published in the OJ (Official Journal) of the European Union on 20.08.2020.

Page 1 uses the text of the RDM. Page 2 includes, in the form of a flowchart, the reprocessing steps, as well as a comparison of the normative tools used as a reference to prove the compliance of the process with the safety and performance requirements. Pages 3, 4 & 5 are a summary of the regulatory provisions set forth in the Implementing Regulation of the European Commission insofar as the member state has authorised this practice.

1. Regulatory data:

- Article 17 is dedicated to the reprocessing of single-use medical devices (MD).
  - It begins by specifying in 1. that: "*reprocessing and further use of single-use devices may only take place where permitted by national law*"
  - And it is added in 2. that "*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*".

- Nevertheless, healthcare facilities are not subjected to all of the requirements of the regulation, and a derogatory measure is set forth 3.: "*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*".

- However, it is up to Member States to ensure that
  a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in (...) Article 5(5) (cf. Explanatory note on manufacturing of MD without externalisation)
  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.

- It is added moreover that: "*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*".

- Lastly, in regard to European governance, State Members shall inform each other and the Commission of the provisions introduced on a national level on these matters, as well as justify their decisions, which will be made public.

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- It is also specified in 4. that it is possible to apply these derogatory measures to single-use MD 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.*"

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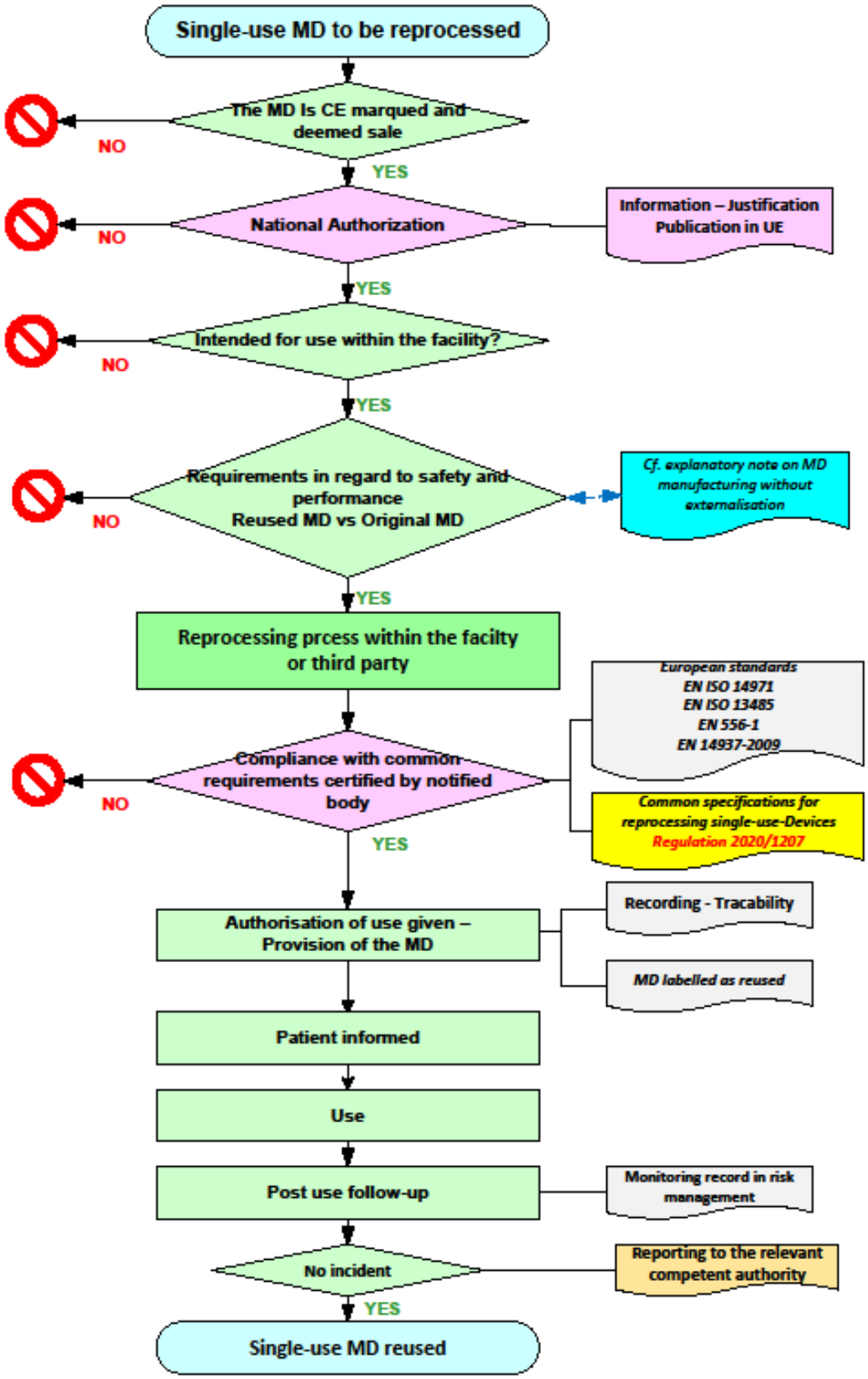
2. Flowchart :



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3. Regulatory provisions set forth by the European Commission's Implementing Regulation 2020/1207 (to be applied from 05.26.2021 onwards)

The main points of this Implementing Regulation are about :

1. The outsourcing by health institutions to a third party. It is specified that one should outsource (Art. 3) based on the consideration the following points :
   a. the attribution of tasks, obligations, and responsibilities of the two parties ;
   b. the arrangements for transition from one external reprocessor to another and responsibilities of the external reprocessor that is a party to the contract ;
   c. the requirements related to the qualification and expertise of the personnel participating in the reprocessing activities ;
   d. the requirements for the reprocessing, collection of information related to the reprocessed devices and information exchange between the health institution and the external reprocessor ;
   e. the requirement to ensure compatibility of the quality management systems (QMS) of the parties, as referred to in Article 21 ;
   f. the procedure for monitoring of the quality of the reprocessing performed by the external reprocessor via on-site audit(s).

2. The common requirements that are summarised in the following table

Requirements	**Key elements**
Staff, premises and equipment *(Art. 4)*	Staff ● In sufficient number, trained accordingly in the relevant tasks, which are laid down in writing when assigned to them ● The person or persons designated as responsible for the reprocessing shall be experienced and qualified in that domain and task, as well as alert and available at all times, and will also be in charge of managing the technical documentation and the QMS Premises : ● Adapted to reprocessing ● Condition of the premises must be adequate and monitored (surfaces, gases, fluids) Equipment : ● Validated, checked and revalidated where applicable
Validation of the process *(Art. 5)*	Assessing the suitability of the device for reprocessing : ● The MD is CE marked and still available on the market ● Restrictions have not been placed on the use of the MD ● Analysis of the suitability based on all available documentation in regard to the design, manufacturing and component materials, as well as any other risk factor, including previous use

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	The decision to reprocess shall depend on the written opinion of the person responsible for reprocessing
Monitoring of the original MD *(Art. 6)*	The health institution must ensure that : ● The original intended purpose of the reprocessed MD has not changed ● The single-use MD is still available on the market and is not subjected to restrictions of use ● Any modification made by the manufacturer during the design or manufacturing of the original MD has no negative consequence on its reprocessing
Determination of reprocessing cycle *(Art. 7)*	The reprocessing cycle shall be determined : - On the one hand based on the information concerning the validation of the reprocessing (Art. 5) - On the other hand based on the results of a technical assessment (physical, electrical, chemical, as well as biological and microbiological tests, and reverse engineering)
Determination of reprocessing cycle *(Art. 7)*	The reprocessing cycle shall be established in written form and validated by the health institution, and describe all steps as well as all procedures for each of these steps in order to ensure that the safety and performance requirements expected of a single-use MD will still be met. The cycle will be monitored throughout, and the single-use MD shall be released once everything is confirmed to be as required.
Maximum number of reprocessing cycles *(Art. 8)*	The health institution is required to determine the maximum number of reprocessing cycles the single-use MD can be put through, and ensure the withdrawal of the MD once that maximum number is reached.
Technical documentation *(Art. 9)*	Technical documentation, which is to be kept for 10 years, includes : - The procedure to monitor the premises and equipment - All decisions concerning the ability or inability to reprocess a single-use MD - The documentation of the original manufacturer as indicated by the Unique Device Identification System 'UDI-DI' - The data used to make a decision about and validate the reprocessing cycle - The data linked to the tracking of the MD through its reprocessing - The description of the system in charge of reporting serious incidents
Reprocessing procedure *(Chapter III; Art. 10 to 20)*	This chapter begins with an article regarding the implementation of a systematic procedure. Subsequently, after having described the steps of the reprocessing cycle, namely: a) pre-treatment at the point of use ; b) transportation, including procedures for safe transportation of hazardous materials ; c) preparation before cleaning ; d) cleaning ; e) thermal disinfection or chemical disinfection ; f) drying ; g) inspection, maintenance, repair and functionality testing ; h) packaging ; i) labelling and provision of instructions for use ; j) sterilization ;

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	k) storage. Each step is described in terms similar to what is expected for the reprocessing of reusable MDs. It is however noted each time that the suitability of each step to the nature of a single-use MD must be ensured.
Focus on labelling	The MD shall be labelled as 'reprocessed' and 'disinfected or sterilized' followed by the method used - its shelf life - the name of the health institution - the maximum number of reprocessing cycles authorised and the number of cycles already performed.
Quality Management System *(Chapter IV; Art. 21 to 23)*	- The health institution shall implement a QMS that meets the requirements set forth in Implementing Regulation (EU) 2017/745 - The QMS shall cover the organisation of all steps a) strategy for regulatory compliance ; b) procedures for each step of the reprocessing cycle ; c) description of the responsibilities, of the personnel involved in reprocessing (tasks, qualification, training and continuous training), and description of the premises ; d) establishment and maintenance of the technical documentation referred to in Article 9 ; e) control of documents and communications concerning the reprocessing activities ; f) control of records concerning the reprocessing activities ; g) reporting of incidents and management of corrective and preventive actions and verification of their effectiveness ; h) risk management ; i) traceability system, including procedures for disposing or returning to the external reprocessor reprocessed single-use devices that do not belong to the health institution ; j) internal and external audits ; k) contract conditions with external entities participating in the reprocessing activities.
Focus on the Audit	Annual, independent, external audit to be carried out by a **notified body**. The report and information on the possible follow-up actions are to be kept for 5 years.

Focus on the Reporting of incidents	Any serious incident shall be reported.
	Such a report shall comply with the following requirements :
	- *confirmation that the single-use device is reprocessed and by which entity;*
	- *specify the number of reprocessing cycles performed and the maximum number of reprocessing cycles allowed for the device concerned;*
	- *the description of the serious incident, including a description of the failure mode, description of how the devices was being used and the point in the procedure when the failure occurred, as well as the outcome for the patient;*
	- *include an analysis of the possible root causes for the serious incident, indicating any of the following:*
	  - *the root cause is linked to the single-use device original design and manufacturing;*
	  - *the root cause is linked to the reprocessing;*
	  - *the root cause could not be clearly established;*
	- *include information regarding preventive and corrective measures to be implemented in the reprocessing process and the timeline to implement these measures or provide reasons as to why measures are not needed.*
	The manufacturer of the original MD shall be informed.

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	The MDs involved in the incidents shall be put away and kept for 5 years. All incidents involving reprocessed MDs shall be recorded and subjected to a critical analysis (including an analysis of any trend) at least once a year. Results of this analysis shall be transmitted to the manufacturer of the original MD and, if requested, to the relevant authority.
Focus on Traceability	The tracking system to be implemented shall ensure the ability to : - record the number of reprocessing cycles the MD has gone through - check that the MD received by the health institution is the same that was sent to an external party to be reprocessed - monitor serious incidents
Recording	● All records of all steps of the reprocessing cycle shall be kept for a duration of at least ten years following the last reprocessing of a single-use device. ● Those records shall be made available to the notified body competent to certify that the common requirements are met and, upon request, to the relevant authorities.