Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1207

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laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[(1)], and in particular Article 17(5) thereof,

Whereas:

(1) Regulation (EU) 2017/745 allows reprocessing of single-use devices only where it is permitted by national law. As regards single-use devices that are reprocessed and used within a health institution, Regulation (EU) 2017/745 allows Member States not to apply all of the rules relating to manufacturers' obligations laid down in that Regulation. One of the conditions for such reprocessing is that it is performed in accordance with common specifications ('CS').

(2) To ensure the quality of the reprocessing activities, CS concerning risk management should include minimum requirements for staff, premises and equipment.

(3) Certain single-use devices are not suitable for reprocessing. CS concerning risk management should therefore include the analysis of the characteristics of single-use devices in terms of construction, material, properties and planned application, in order to assess the suitability of such single-use devices for reprocessing. It is therefore necessary to determine the characteristics of single-use devices to be taken into account within risk management procedures, as to ensure the exclusion of those single-use devices that cannot safely be reprocessed due to their particular hazard potential or specific technical characteristics. Risk management should take into account the risks related to material composition, leachable material, microbiological contamination, prions and transmissible spongiform encephalopathy agents, endotoxins, pyrogenic reactions, allergic reactions and toxic reactions, to assess whether single-use device is suitable for reprocessing. The technical characteristics and geometrical properties of the products should also be taken into consideration when assessing suitability

of single-use devices for reprocessing. Based on these circumstances, examples of single-use devices that could be considered unsuitable for reprocessing include the following: devices emitting radiation, devices used for administering cytostatic or radiopharmaceutical medicines, devices incorporating medicinal substances, devices for use in invasive procedures on the central nervous system, devices that pose a risk of transmission of spongiform encephalopathies, implantable devices, devices for which serious incidents have occurred after reprocessing and the cause of the incident is related to the reprocessing or it cannot be excluded that the cause of the incident is related to the reprocessing, devices with batteries which cannot be changed or present a risk of malfunctioning after reprocessing, devices with internal data storage necessary for the use of the device and which cannot be changed or presents a risk of malfunctioning after reprocessing, devices with cutting or scraping blades, drills or components wearing off that are no longer suitable after the first use and cannot be changed or sharpened before the next medical procedure.

(4) To ensure the safety and performance of the reprocessed single-use device, CS concerning risk management should include the procedure by which the reprocessing cycle is established. In particular, the reprocessing cycle should be based on the characteristics of the single-use device and the results of a technical assessment. To ensure that the performance and safety of the reprocessed single-use device remains equivalent to the original single-use device, it is necessary to determine a maximum number of reprocessing cycles which can be applied to the reprocessed single-use device while the performance and safety remain equivalent to the original single-use device.

(5) The general safety and performance requirements set out in Regulation (EU) 2017/745 apply to reprocessed single-use devices. Health institutions, together, when applicable, with the external reprocessors, are responsible for the safety and performance of the reprocessed device. The health institutions and external reprocessors should therefore have a quality management system ensuring that the relevant requirements are complied with. The quality management system should cover all parts and elements of the organisation regarding the reprocessing. In particular, the quality management system should show that the applicable processes for the reprocessing of single-use devices have been followed and that all conditions for a safe and effective reuse of the reprocessed device have been met. The quality management systems of a health institution and the external reprocessor acting on its behalf should be compatible, in order to ensure continuity of the reprocessing quality.

(6) In order to ensure the safety and performance of reprocessed single-use devices, each health institution using single-use devices reprocessed by the health institution itself or by an external reprocessor at the request of that health institution should have a system in place allowing them to collect information on incidents arising in connection with such devices and should report serious incidents to the competent authority. The manufacturer and, when applicable, the external reprocessor should also be notified of serious incidents.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1207. (See end of Document for details)*

(7) The health institutions and the external reprocessors should have a system in place to ensure traceability of the reprocessed single-use device, notably as regards the reprocessing cycles conducted on a single-use device, and the final disposal of the reprocessed single-use device.

(8) The Medical Device Coordination Group has been consulted.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules for the application of Article 17(3) of Regulation (EU) 2017/745, where national law has permitted reprocessing of single-use devices and a Member State has decided not to apply all of the rules relating to manufacturers' obligations laid down in that Regulation as regards single-use devices that are reprocessed and used within a health institution.

This Regulation also lays down rules where a Member State has chosen to apply Article 17(3) of Regulation (EU) 2017/745 also as regards single-use devices that are reprocessed by an external reprocessor.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'reprocessor' means the health institution and the external reprocessor reprocessing single-use devices;

(2) 'external reprocessor' means the entity reprocessing single-use devices at the request of a health institution;

(3) 'reprocessing cycle' means a cycle that includes all reprocessing steps applied to a single-use device to ensure that the safety and performance of the reprocessed device is equivalent to that of the original device.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1207. (See end of Document for details)*

CHAPTER II

ORGANISATION OF REPROCESSING AND RISK MANAGEMENT

Article 3

Contracting external reprocessors

1 If reprocessing is carried out by an external reprocessor, the health institution and the external reprocessor shall conclude a written contract.

2 The contract shall include the following elements:

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).

Article 4

Staff, premises and equipment

1 Reprocessors shall ensure that the personnel involved in the reprocessing:

a is sufficient in number to ensure the quality of the reprocessing;

b has the relevant specific knowledge and sufficient professional training in view of the reprocessing steps applied;

c has clearly defined tasks and responsibilities laid down in writing.

2 Reprocessors shall designate one or more persons responsible for the reprocessing.

3 The person responsible for reprocessing shall comply with the following criteria:

a has sufficient experience and qualification in the domain of reprocessing;

b has received training on reporting incidents and on undertaking critical analysis in accordance with Article 23(8).

The person responsible for reprocessing shall be permanently and continuously available to the reprocessor during working hours of the reprocessor. The person responsible for reprocessing shall also be responsible for the elaboration and management of the technical documentation referred to in Article 9 and of the QMS referred to in Article 21.

4 The premises where the reprocessing is taking place and the equipment to be used shall be adapted to the type of single-use devices to be reprocessed, the steps of the reprocessing cycle and the number of reprocessing steps.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1207. (See end of Document for details)*

5 The surfaces of the premises, ambient air (temperature, humidity, viable and non-viable airborne particles), water and other gases and fluids shall be controlled and periodically monitored to verify that their microbiological and physical quality is adequate for reprocessing.

6 The equipment shall be subject periodically to generally acknowledged state-of-the-art maintenance, performance checks, and calibrations, according to the manufacturer's instructions. The equipment shall be validated and, where applicable, periodically revalidated, in order to establish that it is suitable for the intended purpose.

7 The reprocessor shall describe in the technical documentation referred to in Article 9(1) the types of single-use devices for which the reprocessor has decided that it has the ability to conduct reprocessing and the justification for that decision. The reprocessor shall make publicly available the list of devices that it is able to reprocess.

8 If the reprocessor decides that it has no longer the ability to reprocess certain types of single-use devices it shall describe the reasons of that decision in the technical documentation referred to in Article 9(1). The list referred to in paragraph 7 of this Article shall be updated accordingly.

Article 5

Preliminary assessment of the suitability of a single-use device for reprocessing

1 Before deciding to start reprocessing a single-use device, or requesting an external reprocessor to do so, the health institution shall assess if the single-use device is suitable for reprocessing.

2 For the purposes of paragraph 1, the health institution shall analyse whether the safety and performance of the single-use device once reprocessed will be equivalent to the original single-use device.

3 When assessing the suitability of a single-use device for reprocessing the health institution, where applicable, shall:

a verify that the single-use device is CE marked;

b verify that the single-use device has not been withdrawn from the market and its certificate of conformity has not been suspended, withdrawn or subject to restrictions;

c verify if the use of the single-use device has been subject to restrictions for safety reasons as indicated in the field safety notices;

d conduct an analysis of the properties of the single-use device, taking into account all available documentation and information on the single-use device to ensure sufficient understanding and know-how on design, constructional properties, material characteristics, functional properties, and other risks factors related to the reprocessing of the single-use device, including its previous use.

Where applicable, when carrying out an assessment in accordance with the first subparagraph, the health institution shall consult an external reprocessor and rely on its operational support in accordance with the contract referred to in Article 3.

For the purpose of points (b) and (c), the health institution shall verify the information in the European Database on Medical Devices (EUDAMED). Until EUDAMED is fully functional, the health institution shall verify the information in accordance with the provisions on exchange of information referred to in Article 123(3)(d) of Regulation (EU) 2017/745.