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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

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 medical devices

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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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 medical 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 5 April 2017 of the European Parliament and of the Council 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/EEC¹, 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, for example, 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 which cannot be changed, 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. 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, so as to ensure the exclusion of those single-use devices that cannot safely be reprocessed

¹ OJ L 117, 5.5.2017, p. 1.

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 specificities and geometrical properties of the products should also be taken into consideration when assessing suitability of single-use devices for reprocessing.

- (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 process is established. In particular, the reprocessing process 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 device, it is necessary to determine a maximum number of reprocessing cycles which can be applied to the reprocessed 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 reproducers, are responsible for the safety and performance of the reprocessed device. The health institutions and external reproducers 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 reproducer 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 reproducer at the request of that health institution should have a system in place allowing them to collect information on serious incidents arising in connexion with such devices and should report serious incidents to the competent authority.
- (7) The health institutions and the external reproducers 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, the patients on which the reprocessed single-use device has been used and the final disposal of the reprocessed single-use device.
- (8) 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.

CHAPTER II

Article 3

RISK MANAGEMENT

Reprocessing by external reproducers

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 requirements related to the qualification and expertise of the personnel participating in the reprocessing activities;
 - (c) the requirements for the reprocessing, collection of information related to the reprocessed devices and information exchange between the health institution and the external reprocessor;
 - (d) the compatibility of the quality management systems (QMS) of the parties, as referred to in Article 21;
 - (e) 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 to ensure the quality of the reprocessing;
 - (b) has the relevant specific knowledge and sufficient professional training in view of the processes applied;
 - (c) has clearly defined tasks and responsibilities laid down in writing.
2. Reprocessors shall designate a person responsible for the reprocessing.
3. The person responsible for reprocessing:
 - (d) shall have sufficient experience and qualification in the domain of reprocessing;
 - (e) shall 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 processes and the number of reprocessing operations.
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 the microbiological and physical quality is sufficient for reprocessing.
6. The equipment shall be subject periodically to state-of-the-art maintenance, performance checks, and calibrations, according to the manufacturer's instructions. The equipment shall be validated periodically in order to establish that it is suitable for the intended purpose, taking into consideration the applicable standards.
7. Where a reprocessor has established that it does not have the capacity to reprocess a type of single-use devices, it shall describe the reason of this decision in the technical documentation referred to in Article 9.
8. Where a reprocessor has established that it has the capacity to reprocess a device, it shall draw up a publicly available list of devices that can be reprocessed by that reprocessor.

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 this purposes, 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. For the purpose of assessing the suitability of a single-use device for reprocessing the health institution 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 as indicated in the European Database on Medical Devices (EUDAMED) or on the website of the manufacturer or of its authorised representative;

- (c) verify that the single-use device is not subject to restrictions for safety reasons as indicated in EUDAMED or on the website of the manufacturer or its authorised representative;
- (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.

For the purposes of point (d) of the first subparagraph, the health institution shall request access to the relevant parts of the technical documentation from the manufacturer, and undertake a review of relevant information in the public domain.

4. When deciding to reprocess a single-use device the health institution shall take into account a written opinion provided by the person responsible for reprocessing on the suitability of a single-use device for reprocessing.

Article 6

Original Intended Purpose and Monitoring of changes made by the manufacturer of the original device

1. Reprocessors shall not change the original intended purpose of the single-use device as indicated in its instructions for use.
2. Reprocessors shall establish a monitoring process to identify any change made by the manufacturer to components, materials, or specifications of the single-use device that may have an impact on reprocessing. Reprocessor shall assess the significance of the change for the appropriateness of reprocessing. If the change has a detrimental effect on the reprocessed single-use device, reprocessing shall be discontinued or the reprocessing process shall be modified to adapt to the change made to the single-use device.

Article 7

Reprocessing process

1. Health institutions reprocessing single-use devices, together, when applicable, with external reprocessors, shall determine the process by which the single-use device is to be reprocessed.
2. The process shall be determined based on the documentation and information collected in accordance with Article 5 and the results of a technical assessment including, when appropriate, physical, electrical, chemical, and biological tests, and reverse engineering. The procedure shall not change the intended purpose of the single-use device, shall take into account the scientific and technical knowledge, and, if applicable, the original method of sterilisation and the relevant standards.
3. The process for reprocessing shall be established in written documents and be validated by the health institution reprocessing single-use devices, together, when applicable, with external reprocessor. The process shall describe each step of the reprocessing, including storage and transportations conditions and, as applicable,

safe disassembly and reassembly steps. For each step, the relevant procedure shall be established.

Article 8

Maximum number of reprocessing cycles

1. The health institution, together with the external reprocessor, when applicable, shall determine the maximum number of reprocessing cycles which can be applied to the reprocessed single-use device, during which the performance and safety of that single-use device remains equivalent to the original device.
2. Once the maximum number of reprocessing cycles has been reached, the reprocessed single-use device shall be disposed of.

Article 9

Technical documentation

1. Reprocessors shall have a technical documentation on its reprocessing activities which shall include:
 - (a) the procedures for controlling and periodically monitoring premises and equipment referred to in Article 4(5) and (6);
 - (b) any decision concerning the lack of capacity to reprocess a type of single-use devices.
2. Reprocessors shall also have a technical documentation specific to each single-use device. The technical documentation shall include:
 - (a) the findings of the identification of the reprocessing process and procedures referred to Article 7;
 - (b) the actions to be undertaken in case one or more steps of reprocessing have not been performed in accordance with the process.

The technical documentation specific to each single-use device kept by health institutions shall also include:

- (a) the findings of the assessment of the suitability of the single-use device for reprocessing described in Article 5 and the reasons for the assumption that the information assembled and the studies performed are sufficient to prove that the safety and performance of the reprocessed device will be equivalent to those of the original device;
 - (b) the system to identify and to dispose of the single-use devices if it fails to meet any aspect of functionality, performance, or safety during reuse.
3. The technical documentation shall be kept for 10 years after the last reuse of a single-use device.

CHAPTER III

REPROCESSING PROCEDURES

Article 10

Validation of procedures

1. Prior to starting the reprocessing, reprocessors shall perform a visual check of the single-use devices for damages. They shall test whether movable parts can be correctly moved. If maintenance or adjustment is needed for the single-use device to perform as specified in the instruction for use, the maintenance shall be performed according to the established procedure. The reprocessors shall dispose of damaged or dysfunctional single-use devices.
2. The reprocessor shall establish validated decontamination procedure adapted to the nature of the single-use device and the risks linked with its use.
3. Preparation for reprocessing shall not compromise the hygienic state and the functionality of the decontaminated device. If there is a delay exceeding an established time limit in the procedure before cleaning and disinfection or sterilization, adequate pre-cleaning and intermediate storage shall be carried out. The single-use devices shall be transported to the reprocessing premises in closed identified and dedicated containers under the conditions set out in a procedure.
4. The necessary requirements in terms of microbiological and chemical properties of water, chemicals, and other products used in the reprocessing shall be set out in the procedures for each specific process.
5. When choosing cleaning, disinfection and sterilization procedures, priority shall be given to validated automated procedures that ensure their reproducibility. The disinfection shall ensure appropriate bactericidal (including mycobacteria), fungicidal, and virucidal effects, and the effectiveness of the disinfection shall be verified regularly on samples.
6. Cleaning and disinfectant solutions, and the sterilizing agent if applicable, shall be removed by a validated method described in a procedure.
7. The sterilization with moist heat (steam sterilization) shall be used where such use is appropriate. However, other validated methods may be chosen according to the properties and characteristics of the single-use device to be reprocessed.
8. Monitoring of sterilization cycles and release of sterilized single-use devices shall be based on attaining the sterilization parameters within the established and validated tolerances described in a procedure. If applicable, those physical measurements shall be supplemented by using qualified biological indicators to verify that all sterilization parameters were attained within the established tolerances determined in the procedure.
9. The packaging system shall be suitable for the content, validated according to relevant standards and the sterilization method used if applicable, for the properties of the reprocessed single-use device and for the intended storage and transportation. The packaging shall enable sterilization and guarantee sterility until use, under proper storage and transportation conditions. If during the reprocessing a problem concerning the functionality, performance, or safety of the single-use device is

detected, the problem shall be addressed and the single-use device shall be repaired, if possible, or disposed of if repair is not possible. The cause of the problem shall be investigated in order to verify the continued efficacy of the process. If the process is no longer achieving its objective, the process shall be modified or reprocessing shall be stopped for that specific single-use device. If any of the steps of the reprocessing fails to meet the requirements laid down in the procedures for that single-use device, it shall not be released for reuse.

Article 11

Steps of the reprocessing process

The procedures for the reprocessing process shall cover the following steps, if applicable to the device concerned:

- (a) treatment at the point of use prior to reprocessing;
- (b) preparation before cleaning;
- (c) cleaning;
- (d) thermal disinfection;
- (e) chemical disinfection;
- (f) drying;
- (g) inspection, maintenance, repair and functionality testing;
- (h) labelling;
- (i) packaging;
- (j) sterilization validation according to harmonized standards;
- (k) validation, consisting of installation, operational and performance qualification;
- (l) periodic routine tests and contamination control;
- (m) metrological monitoring and testing of processing parameters;
- (n) storage;
- (o) release;
- (p) transportation;
- (q) calibration;
- (r) traceability system;
- (s) identification and tracking throughout the lifetime of the single-use device.

Article 12

Treatment at the point of use prior to reprocessing

Procedures for pre-treatment at the point of use prior to reprocessing referred to in point (a) of Article 11 shall cover the following:

- (a) description of the pre-treatment techniques;

- (b) any checks that need to be undertaken;
- (c) the maximum period of time that may elapse between use and cleaning;
- (d) description of the support systems and containers for transportation;
- (e) requirements for transportation.

Article 13

Preparation before cleaning

Procedures for preparation before cleaning reprocessing referred to in point (b) of Article 11 shall cover the following, if applicable:

- (a) requirements for disassembly of the single-use device;
- (b) capping or opening of ports;
- (c) leak testing;
- (d) special soaking or brushing techniques and ultrasonic treatment of the single-use device.

Article 14

Cleaning

Procedures for cleaning referred to in point (c) of Article 11 shall cover the following, if applicable:

- (a) techniques to be used, including rinsing;
- (b) description of the accessories required for cleaning process;
- (c) identification and concentration of chemicals required for cleaning;
- (d) identification of water quality to be used;
- (e) limits and monitoring of chemical residues remaining on the single-use device;
- (f) limits on temperature and concentration of solution(s);
- (g) exposure time to be used;
- (h) temperature(s) to be used.

Article 15

Thermal disinfection

Procedures for thermal disinfection referred to in point (d) of Article 11 shall cover the following, if applicable:

- (a) limits on temperature and exposure time;
- (b) description of the accessories required for the disinfection process;
- (c) identification of water quality required;

- (d) techniques to be used including rinsing volume and time with criteria and/or requirements for approval or rejection.

Article 16

Chemical disinfection

Procedures for chemical disinfection referred to in point (e) of Article 11 shall cover the following, if applicable:

- (a) identification and concentration of chemicals required for the disinfection process;
- (b) contact time of the disinfectant;
- (c) temperature(s) to be used;
- (d) limits on temperature, concentration of solution(s), exposure time;
- (e) description of the accessories required for the disinfection process;
- (f) identification of water quality required;
- (g) techniques to be used including rinsing volume and time;
- (h) limits and monitoring of chemical residues remaining on the single-use device after disinfection;
- (i) limits and monitoring of chemical residues remaining on the single-use device from cleaning agents to ensure these residues do not interact adversely with the disinfectant;
- (j) criteria and/or requirements for approval or rejection.

Article 17

Drying

Procedures for drying referred to in point (g) of Article 11 shall cover the following:

- (a) criteria and/or requirements for the maximum temperature and exposure time;
- (b) specification of the drying agent.

Article 18

Inspection, maintenance, repair and functionality testing

Procedures for inspection, maintenance, repair and functionality testing referred to in point (f) of Article 11 shall cover the following, if applicable:

- (a) method(s) and performance criteria for inspection;
- (b) method(s) to be used for adjustment and/or calibration;
- (c) type, amount and method of application of lubricant;
- (d) re-assembly of the single-use device.

Article 19

Packaging

1. Procedures for packaging referred to in point (i) of Article 11 shall cover the following, if applicable:
 - (a) material specification;
 - (b) declaration of conformity with the specific sterilization or disinfection method;
 - (c) sealing temperature
 - (d) criteria for acceptance or rejection .
2. The packaging and the instructions for use shall not bear the CE mark.

Article 20

Labelling and instructions for use

1. Reprocessed single-use devices shall bear the word “reprocessed” on their label, as well as the status of the single-use device: "disinfected" or "sterilized", followed by the sterilization method or disinfection method, and shelf life.
2. The name and address of the health institution, and the external reprocessor if applicable, shall be clearly indicated on the label and, where applicable, in the instructions for use of the single-use device.
3. Where possible, the name and address of the manufacturer of the original device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed single-use device.
4. The maximum number of reprocessing cycles allowed and the number of reprocessing cycles performed shall clearly appear on the label.

CHAPTER IV

QUALITY MANAGEMENT SYSTEM

Article 21

Quality management system

1. Reprocessors shall establish, document, implement, and maintain a QMS for the reprocessing activities.
2. The QMS shall ensure that requirements set out in this Regulation and requirements applicable to reprocessing set out in Regulation (EU) 2017/745 are complied with.
3. The QMS shall cover the organisation of all steps of reprocessing and shall address at least the following aspects:
 - (a) strategy for regulatory compliance
 - (b) procedures for each step of the reprocessing processes;
 - (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) internal and external audits;
 - (j) contract conditions with external entities participating in the reprocessing activities.

Article 22

Annual audit

1. Reprocessors shall undertake at least one annual independent external audit of the reprocessing activities. The audit report shall be made available to the competent authorities on request.
2. The results of the independent external audit shall be taken into consideration to improve the reprocessing processes and the QMS.
3. The audit report and the documentation related to the eventual follow up actions shall be kept for a period of five years.

Reporting of incidents

1. Health institutions using reprocessed single-use devices shall report all serious incidents involving reprocessed single-use devices to the manufacturer, to the relevant competent authority and, when applicable, to the external reprocessor.
2. The incident report shall:
 - (a) indicate that the single-use device is reprocessed and by which entity;
 - (b) specify the number of reprocessing cycles performed;
 - (c) include an analysis of the possible root causes for the serious incident, indicating any of the following:
 - (1) the root cause is linked to the original design and manufacturing;
 - (2) the root cause is linked to the reprocessing;
 - (3) the root cause could not be clearly established;
 - (d) include information regarding preventive and corrective measures to be implemented in the reprocessing process or provide reasons as to why measures are not needed.
3. Reprocessed single-use devices involved in a serious incident shall be set apart and shall not be used further. They shall be kept available for authorities for five years, unless otherwise instructed by the competent authority.
4. During investigation of the serious incident, devices of the same type reprocessed by the same process shall be set apart. If the investigation of the serious incident has not excluded reprocessing as root cause for the serious incident, these reprocessed devices shall be disposed of.
5. The health institution shall request its staff and, where appropriate, invite its patients to report any incident involving reprocessed single-use devices. To that end, it shall communicate one contact person within the health institution.
6. The external reprocessor shall report to the health institution any failure occurring during reprocessing that could indicate that the reprocessing process is no longer adequate or that the safety and performance of single-use devices already released for use cannot be guaranteed anymore. In that case, adequate corrective and preventive measures shall be taken immediately.
7. The health institution shall register and compile information about all incidents involving reprocessed devices and shall perform, at least annually, a critical analysis of those incidents. The critical analysis of all incidents, including the analysis of the trends of incidents, shall be transmitted to the relevant notified body and if applicable to the external reprocessor. The analysis shall be used by the health institution, and if applicable, by the external reprocessor, to improve the processes of reprocessing, to review and update the technical documentation and/or to decide to discontinue reprocessing certain types of single-use devices.

CHAPTER V

TRACEABILITY

Article 24

Tracking of reprocessing cycles

1. Reprocessors shall put in place a tracking system allowing the identification of the single-use device throughout the reprocessing process.

This tracking system shall also record the following:

- (a) the number of reprocessing cycles that the single-use device has undergone;
 - (b) on which patients the single-use device has been used.
2. The tracking system shall allow the health institution to verify if the single-use device reprocessed by the external reprocessor and returned to the health institution is the same single-use device that was used in the health institution concerned and sent to the external reprocessor for reprocessing.
3. The tracking system shall ensure that reprocessed devices can be linked to the correct batch number for the purposes of field safety corrective action in accordance with Article 89 of Regulation (EU) 2017/745, or for the purpose of recall by the manufacturer.

Article 25

Records

Reprocessors shall store all records regarding all steps of the reprocessing process, for a period of at least five years after the last reprocessing of a single-use device. The health institution and the external reprocessor, shall make those records available to their notified body and to relevant authorities upon request.

CHAPTER VI

FINAL PROVISIONS

Article 26

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 26 May 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission
The President
Jean-Claude JUNCKER*

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