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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1206

of 19 August 2020

amending Implementing Regulation (EU) 2019/1323 on exceptional market support measures for the eggs and poultrymeat sectors in Italy

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 220(1)(a) thereof,

Whereas:

(1) Within the context of outbreaks of avian influenza in Italy, the Commission adopted two Regulations on exceptional market support measures. Commission Implementing Regulation (EU) 2018/1506 ([2]) covers outbreaks between 30 April 2016 and 28 September 2017 and Commission Implementing Regulation (EU) 2019/1323 ([3]) covers outbreaks between 1 October 2017 and 30 June 2018.

(2) Italy informed the Commission that in the course of the application of those Regulations a number of holdings that were affected by outbreaks before 28 September 2017 and compensated within the framework of Implementing Regulation (EU) 2018/1506 were also affected by veterinary restrictions in the form of continuing compulsory closure and resulting economic losses beyond 28 September 2017 and falling into the time period covered by Implementing Regulation (EU) 2019/1323.

(3) The Commission received a formal request from Italy to include those holdings within the scope of Implementing Regulation (EU) 2019/1323 to allow compensation of their continuing economic losses beyond 28 September 2017. Implementing Regulation (EU) 2018/1506 limited the eligibility for Union part-financing to expenditure that has been paid by Italy to the beneficiaries by 30 September 2019 whereas Implementing Regulation (EU) 2019/1323 still allows payments until 30 September 2020.

(4) Implementing Regulation (EU) 2019/1323 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) Commission Implementing Regulation (EU) 2018/1506 of 10 October 2018 on exceptional market support measures for the eggs and poultrymeat sectors in Italy (OJ L 255, 11.10.2018, p. 1).
([3]) Commission Implementing Regulation (EU) 2019/1323 of 2 August 2019 on exceptional market support measures for the eggs and poultrymeat sectors in Italy (OJ L 206, 6.8.2019, p. 12).

HAS ADOPTED THIS REGULATION:

Article 1

Article 1 of Implementing Regulation (EU) 2019/1323 is replaced by the following:

'*Article 1*

The Union shall provide part-financing equivalent to 50 % of the expenditure borne by Italy to support the market of hatching eggs, consumption eggs and poultry meat seriously affected by the 45 outbreaks of highly pathogenic avian influenza of subtype H5 which were detected and notified by Italy between 1 October 2017 and 30 June 2018 and outbreaks notified by Italy between 20 July 2017 and 28 September 2017 which resulted in the compulsory closure of holdings beyond 28 September 2017.'.

Article 2

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

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

Done at Brussels, 19 August 2020.

For the Commission
The President
Ursula VON DER LEYEN

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)

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.

([1]) OJ L 117, 5.5.2017, p. 1.

(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.

(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.

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.

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.

Where the information cannot be obtained in accordance with the third subparagraph, the health institution shall verify the information on the website of the manufacturer or of its authorised representative.

For the purpose of point (d), the health institution shall review the information referred to in point (p) of Section 23.4 of Chapter III of Annex I to Regulation (EU) 2017/745 and all other relevant documentation and information in the public domain.

4. The decision of the health institution concerning the suitability of a single-use device for reprocessing shall be based on a written positive opinion provided by the person responsible for reprocessing. Single-use device shall not be reprocessed if the person responsible for reprocessing has provided a negative opinion on the suitability of the single-use device for reprocessing.

Article 6

Original intended purpose and monitoring of changes made by the manufacturer of the original single-use 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 verify the following:

(a) that the single-use device is not withdrawn from the market;

(b) that the certificate of conformity of the single-use device has not been suspended, withdrawn or is not subject to restrictions;

(c) the use of the single-use device is not subject to restrictions for safety reasons based on the information referred to in Article 5(3), (b) and (c);

The reprocessors shall also identify any change made by the manufacturer to components, materials, intended purpose or specifications of the single-use device that may have an impact on the reprocessing. Reprocessors shall assess the significance of these changes for the appropriateness of reprocessing. If a 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

Determination of reprocessing cycle

1. Health institutions reprocessing single-use devices shall determine, when applicable together with external reprocessors, the reprocessing cycle for single-use device to be reprocessed.

2. The reprocessing cycle 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 and microbiological tests, and reverse engineering. The reprocessing cycle 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 reprocessing cycle shall be established in writing and shall be validated by the health institution reprocessing single-use devices, when applicable, together with external reprocessor. The reprocessing cycle shall describe each step of the reprocessing. For each step, the relevant procedure shall be established and each step shall be validated. Validation of the reprocessing steps shall consist of installation and operational and performance qualification.

4. The validation shall ensure that the performance and safety of the single-use device remains equivalent to the original single-use device after every reprocessing cycle and up to the maximum allowed number of reprocessing cycles.

5. The reprocessing cycle shall be monitored through periodic routine tests and contamination controls, physical, electrical, chemical and biological monitoring and testing of process parameters and calibration.

6. The reprocessed single-use device shall be released after it is confirmed that cleaning, disinfection and sterilization steps and any testing, as appropriate, assure that the reprocessing cycle has been completed in compliance with the requirements applicable to such cycle.

Article 8

Maximum number of reprocessing cycles

1. Each reprocessing in accordance with Article 11 shall be counted as one reprocessing cycle. Each reprocessing cycle of a single-use device shall be counted to determine the maximum number of reprocessing cycles even if a single-use device was not reused on a patient following the reprocessing.

2. 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 single-use device.

3. 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 ability or lack of ability to reprocess a type of single-use devices.

2. Reprocessors shall also have a technical documentation specific to each model of single-use device, manufactured by the same manufacturer, as identified by its device identifier in the Unique Device Identification system ('UDI-DI'). The technical documentation shall include:

(a) the results of the determination of the reprocessing cycle and procedures referred to in Article 7;

(b) the actions to be undertaken in case one or more steps of the reprocessing cycle have not been performed.

3. The technical documentation specific to each model of single-use device manufactured by the same manufacturer, as identified by its UDI-DI that is kept by health institutions, shall also include:

(a) the results of the assessment of the suitability of the single-use device for reprocessing described in Article 5 and the data and information used for the assumption that the safety and performance of the reprocessed device will be equivalent to those of the original single-use device;

(b) the results of the monitoring process referred to in Article 6;

(c) the description of the system for tracking the single-use device from the first use until its last reuse;

(d) the description of the system for reporting serious incidents in accordance with Article 23;

(e) the description of the system to identify and to dispose of the single-use device if it fails to meet any aspect of functionality, performance or safety, prior or during reuse.

4. The technical documentation shall be kept for 10 years after the last reuse of a single-use device.

CHAPTER III

PROCEDURES AND STEPS OF THE REPROCESSING CYCLE

Article 10

Establishment 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 a validated decontamination procedure adapted to the properties and characteristics 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 of single-use device, it shall be adequately pre-cleaned and put in intermediate storage. 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 cycle.

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 not all relevant sterilization parameters can be measured, those physical measurements shall be supplemented by using qualified biological indicators to provide additional assurance that no undetected deviations from the validated cycle occurred.

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 during the stated shelf life and 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 cycle. If the process is no longer achieving its objective, the cycle 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 cycle

The reprocessing cycle shall cover the following steps, if applicable to the device concerned:

(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;

(k) storage.

Article 12

Pre-treatment at the point of use and transportation

Procedures for pre-treatment at the point of use and transportation prior to reprocessing referred to in points (a) and (b) of Article 11 shall cover the following, if applicable:

(a) description of the pre-treatment techniques;

(b) any checks that need to be undertaken;

(c) definition of 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 referred to in point (c) 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 (d) 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 process parameters, including temperature, concentration of solution(s) and exposure time to be used.

Article 15

Thermal disinfection

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

(a) limits on process parameters, including 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 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 (f) of Article 11 shall cover the following, if applicable:

(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 (g) 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, reparation and/or calibration;

(c) type, amount and method of application of lubricant;

(d) re-assembly of the single-use device;

(e) specification of parts that might need to be replaced;

(f) functionality testing and parameters to be considered for acceptance or rejection.

Article 19

Packaging

1. Procedures for packaging referred to in point (h) of Article 11 shall cover the following, if applicable:

(a) material specification;

(b) compliance with the specific sterilization or disinfection method;

(c) limits on packaging process parameters, including sealing temperature;

(d) criteria for acceptance or rejection.

2. The packaging and the instructions for use of the reprocessed single-use device shall not bear the CE mark.

Article 20

Labelling and provision of 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 in the instructions for use of the single-use device.

3. 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, ANNUAL AUDIT AND REPORTING OF INCIDENTS

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 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.

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 notified body competent for the certification of the reprocessor pursuant to Article 17(5) of Regulation (EU) 2017/745 and, upon request, to the competent authority of the Member State where the reprocessor is established.

2. The reprocessing processes and the QMS shall be revised, as needed, on the basis of the results of the independent external audit.

3. The audit report and the documentation related to the eventual follow up actions shall be kept for a period of five years.

Article 23

Reporting of incidents

1. Health institutions using reprocessed single-use devices shall report all serious incidents involving reprocessed single-use devices, to the relevant competent authority. Those incidents shall be reported by the deadlines set in Article 87 of Regulation (EU) 2017/745.

2. The serious incident report shall contain the following information:

(a) confirmation that the single-use device is reprocessed and by which entity;

(b) specify the number of reprocessing cycles performed and the maximum number of reprocessing cycles allowed for the device concerned;

(c) 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;

(d) 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;

(e) 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.

3. When the health institution sends the report referred to in paragraph 1 of this Article to the competent authority, the health institution shall send a copy of that report also to the manufacturer and, when applicable, the external reprocessor. Following receipt of the copy of the report, the manufacturer shall take any of the actions listed in Article 83(3) of Regulation (EU) 2017/745, where necessary.

4. Reprocessed single-use devices involved in a serious incident shall be set apart and shall not be used further. The health institution shall keep such single-use devices for five years and make it available to the competent authority upon request, unless otherwise instructed by the competent authority.

5. During investigation of the serious incident, devices of the same type subject to the same reprocessing cycle shall be set apart. If the investigation of the serious incident has shown reprocessing as the possible root cause for the serious incident, these reprocessed devices shall be disposed of.

6. 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.

7. The external reprocessor shall report to the health institution any failure occurring during reprocessing that could indicate that the reprocessing cycle is no longer adequate or that the safety and performance of single-use devices already released for use cannot be guaranteed anymore. If failure occurs, adequate corrective and preventive measures shall be taken immediately. The health institution shall inform the competent authority accordingly and the public list referred to in Article 4(7) shall be updated.

8. 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 manufacturer and, if applicable, to the external reprocessor. Upon request, the critical analysis of all incidents, including the analysis of the trends of incidents shall be transmitted to the relevant competent authority. The analysis shall be used by the health institution, and if applicable, by the external reprocessor, to improve the reprocessing cycle, to review and update the technical documentation and/or to decide to discontinue reprocessing certain types of single-use devices.

CHAPTER V

TRACEABILITY OF SINGLE-USE DEVICE AND FINAL PROVISIONS

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 cycle and the lifetime of the reprocessed single-use device.

This tracking system shall ensure the following:

(a) record the number of reprocessing cycles that the single-use device has undergone;

(b) ensure that the health institution verifies that 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.

2. 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.

Article 25

Records

Reprocessors shall store all records regarding all steps of the reprocessing cycle, for a period of at least 10 years after the last reprocessing of a single-use device. The health institution and the external reprocessor, shall make those records available to the notified body competent for the certification referred to in Article 17(5) of Regulation (EU) 2017/745 and, upon request, to authorities of the Member States.

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 2021.

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

Done at Brussels, 19 August 2020.

For the Commission
The President
Ursula VON DER LEYEN

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