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Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices

Stérilisation des dispositifs médicaux — Informations devant être fournies par le fabricant pour le processus de restérilisation des dispositifs médicaux

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 17664 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

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Foreword

This document (EN ISO 17644:2004) has been prepared by Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2004, and conflicting national standards shall be withdrawn at the latest by September 2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Informative annexes A and B are attached to this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This standard applies to those medical devices which are intended for multiple use and require processing to take them from their state at the end of one use to the state of being sterile and ready for their subsequent use. Some medical devices supplied non-sterile but intended to be used in a sterile state, will also require similar treatment.

1 Scope

This standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be re-sterilizable and medical devices intended to be sterilized by the processor.

This standard specifies requirements for the information to be provided by the medical device manufacturer, so that the medical device can be processed safely and will continue to meet its performance specification.

Requirements are specified for processing that consists of all or some of the following activities:

— preparation at the point of use;

— preparation, cleaning, disinfection;

— drying;

— inspection, maintenance and testing;

— packaging;

— sterilization;

— storage.

When providing instructions for these activities, medical device manufacturers are expected to be aware of the training and knowledge of procedures, and of the processing equipment available to the persons likely to be responsible for processing. It is likely that some processing procedures will be generic and well known and will use equipment and consumables conforming to recognized standards. In this case, a reference in the instructions is all that is required. For those medical devices where instructions for use are not required to accompany the medical device, other means of communicating the information can be used, e.g. user manuals, symbols or wall charts supplied separately.

This standard excludes textile devices used in patient draping systems or surgical clothing.

NOTE The principles of this standard may be applied when considering the information to be supplied with medical devices which only require disinfection prior to re-use.

2 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

2.1
chemical
formulation of compounds intended for use in reprocessing

NOTE This includes, for example, detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners, sterilants.

2.2
cleaning
removal of contamination from an item to the extent necessary for further processing or for intended use

2.3
disinfection
process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use

2.4
manual cleaning
cleaning without the use of a washer-disinfector

2.5
manufacturer
organization with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on its behalf by a third party

2.6
processing
activity including cleaning, disinfection and sterilization, necessary to prepare a new or used medical device for its intended use

2.7
processor
organization with the responsibility for carrying out the actions necessary to prepare a new or used device for its intended use

2.8
sterilant
chemical which has properties to destroy micro-organisms including viruses, when used at correct dilution/dose and applied for recommended exposure time

2.9
sterile
free from all viable microorganisms

2.10
sterilization
process used to render a device free from all forms of viable microorganisms

NOTE In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. Whist this probability may be reduced to a very low number, it can never be reduced to zero. (See ISO 11134). This probability can only be assured for validated processes.

2.11
validation
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

2.12
verification
confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

2.13
washer-disinfectors
machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice

NOTE 1 This type of machine does not include those designed specifically to wash linen or clothing. Machines intended to sterilize, or designated as sterilizers, are specified in other standards e.g. EN 285.

NOTE 2 Preliminary standards for washer-disinfectors (prEN 15883) are being prepared in an ISO-CEN project.

3 Information to be provided by the medical device manufacturer

3.1 Reprocessing instructions

At least one validated method for reprocessing the medical device shall be specified.

The following information shall be stated where it is critical to the maintenance of the intended function of the medical device and the safety of the user(s) and the patient:

— details of process steps;

— a description of special equipment and/or accessories;

— specification of process parameters and their tolerances.

NOTE Further information is provided in annex A.

3.2 Limitations and restrictions on reprocessing

The manufacturer shall determine if processing in accordance with the provided instructions leads to a degree of degradation that will limit the useful life of the medical device. Where such degradation is established, the manufacturer shall provide an indication of the number of reprocessing cycles that can normally be tolerated, or some other indication of the end of the medical device's ability to safely fulfil its intended use.

3.3 Preparation at the point of use prior to processing

Requirements for preparation at the point of use to ensure satisfactory reprocessing of the medical device, shall be specified, if applicable.

Where appropriate, at least the following information shall be included:

— the containers for transportation;

— a description of the support systems;

— the maximum period of time that may elapse between use and cleaning;

— a description of the pre-cleaning techniques critical to further processing;

— the requirements for transportation.

3.4 Preparation before cleaning

Requirements for the preparation of the medical device prior to cleaning shall be specified if applicable. Where appropriate, instructions for at least the following procedures shall be given:

- the requirements for capping/opening of ports;
- disassembly of the device;
- leak testing the device;
- soaking/brushing techniques required;
- ultrasonic treatment of the device.

If special tools are required for disassembly/re-assembly, these shall be specified in the instructions.

3.5 Cleaning

A validated method of manual cleaning shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued.

Where appropriate, at least the following information shall be included:

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

NOTE Cleaning and Disinfecting Processing Equipment should be qualified and validated to ensure suitability for its intended purpose.

3.6 Disinfection

A validated non-automatic method of disinfection shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process.

Where appropriate, at least the following information shall be included:

- a description of the accessories required for the disinfection process;
- the contact time of the disinfectant;
- identification and concentration of chemicals required for the disinfection process;
- identification of water quality required for the process;

— the limits and monitoring of chemical residues remaining on the device;

— the limits on temperature, concentration of solution(s), exposure time;

— the process temperature(s) to be used;

— the techniques to be used including rinsing.

NOTE 1 In certain circumstances disinfection may be carried out concurrently with cleaning of the medical device.

NOTE 2 Wherever practical a washer-disinfector using thermal disinfection is preferred.

NOTE 3 Certain clinical procedures lead to an enhanced probability of contamination with agents with high resistances against certain disinfectants (e.g. mycobacteria). This should be considered in the risk analysis and in the choice of recommended disinfectant.

3.7 Drying

Where drying is necessary, a validated method of drying shall be specified. Where appropriate at least the following information shall be included:

— the accessories required for the drying process;

— the maximum temperature and exposure time for the device;

— specifications of the drying agent to be used;

— the techniques to be used.

NOTE In certain circumstances drying may be achieved as part of an automated cleaning and disinfection process.

3.8 Inspection, maintenance and testing

When methods are required at any stage of processing to confirm the cleanliness or performance or both, of the medical device, these shall be stated. Where particular maintenance actions are required during processing to ensure the proper performance and safety of the medical device, these shall be stated. Where appropriate, these shall include details such as any part or component that requires routine replacement and/or calibration and where necessary, details for return to the manufacturer or other qualified organization.

Where appropriate at least the following information shall be given:

— the method to be used for adjustment/calibration of the device;

— a description of the lubrication to be used;

— the performance criteria for the device to ensure its safe use;

— the instructions for re-assembly of the device;

— the method to be used for the replacement of components;

— a description of special tools to be used to maintain the device;

— the requirements for visual inspection.

NOTE If instruction to return the medical device to the manufacturer or other qualified organization is specified, the manufacturer should give clear instructions as to the cleanliness and/or microbiological status required.

3.9 Packaging

If a specific method for packaging or containing the medical device during and after sterilization is required, it shall be stated and be compatible with the sterilization process and the medical device.

3.10 Sterilization

A validated method of sterilization shall be specified.

Where appropriate, at least the following information shall be given; this shall include set points and the upper and lower limits of critical process parameters that are capable of achieving sterility of the medical device:

- the accessories required for sterilization of the medical device;
- the identification and concentration of the sterilant required for the sterilization process;
- the identification of maximum values of contaminants in condensate from steam, used in moist heat, ethylene oxide and/or steam and formaldehyde sterilization;
- the humidity required for the sterilization process;
- the minimum holding or exposure time of sterilant;
- a description of post-sterilization techniques/activities;
- pressure required for the sterilization process;
- a description of the techniques to be used;
- the required temperature of the sterilant.

NOTE Wherever possible, moist heat sterilization is recommended.

3.11 Storage

Any specific limitations for the time or conditions of storage of the reprocessed medical device prior to use shall be stated.

4 Presentation of the information

4.1 Where applicable, the information required by clause 3 shall accompany the medical device, e.g. in the instructions for use supplied with the medical device, or on the medical device label or packaging.

NOTE An example format for giving detailed information for a particular medical device is given in annex B.

4.2 The information specified in clause 3 shall take into account the nature of the medical device, its intended use and the knowledge and training of the persons involved in the processing.

NOTE The information specified in clause 3 may make reference to:

— standards available;

— general processing information provided by the manufacturer;

— general processing information provided by the manufacturer of the equipment of materials involved in the specified process.

Such reference may be achieved by the use of symbols (ref: ISO 15223 and ISO 7000).

4.3 The equipment or materials necessary in the specified processes shall be identified by its generic names or specification. Only in those cases where this does not provide sufficient information, trade names may be given in addition.

5 Validation of the reprocessing information provided

The manufacturer shall validate that any process identified in the information provided is capable of reprocessing the medical device for its intended use.

NOTE Where the manufacturer supplies a number of different medical devices which share common features and attributes, the validation specified may be performed with respect to these medical devices as a group or family, provided that the manufacturer can demonstrate the commonality of the medical devices and that the tests and assessments address the “worst case” feature or attribute of the group or family.

6 Risk analysis

In the risk analysis performed by the medical device manufacturer to determine the content and detail of the information to be provided, the medical device manufacturer shall take into account:

— the nature of the medical device;

— the intended use of the medical device;

— the likely training and knowledge of the processor;

— the equipment likely to be available to the processor.

NOTE See EN ISO 14937 as guidance.

Annex A
(informative)

Commonly utilized reprocessing methods

A.1 General

The following example of a matrix is intended to assist the manufacturer of medical devices to identify methods of processing that may be considered for inclusion in the processing instructions provided.

The general acceptability of each of the methods for various categories of medical devices is indicated and may be used as a guide when considering the equipment, training and resources likely to be available to processors of the various medical device categories and so allow selection of processing methods most readily implemented by the processor.

Thorough cleaning prior to disinfection and sterilization is especially important for infection control.

This information also indicates what an experienced processor may assume to be appropriate reprocessing methods for certain medical device categories. As such it may be used as an input to the risk analysis required by this standard (clause 6) to determine the extent of warnings to avoid damaging or unsafe processing methods for a particular medical device.

The information in the following matrix is for guidance only and cannot be universally applied to all makes of medical devices within a category without reference to and compliance with the specific instructions provided.

IT IS STILL THE RESPONSIBILTY OF THE MANUFACTURER TO IDENTIFY AND VALIDATE SPECIFIC PROCEDURES FOR THE PARTICULAR MEDICAL DEVICE BEING CONSIDERED. LIKEWISE PROCESSORS SHOULD REFER TO, AND COMPLY WITH, THE SPECIFIC INSTRUCTIONS PROVIDED BY THE MANUFACTURER OF THE MEDICAL DEVICE, PROCESSING EQUIPMENT AND/OR PROCESSING CHEMICAL.

A.2 Matrix for identifying methods of processing

Table A.1 — Examples of processes that might be applied

Process			Medical device							
			A Reusable surgical instruments	**B** Endoscopes (thermostable)	**C** Endoscopes (thermolabile	**D** Instruments for use with endoscopes	**G** Reusable containers	**H** Elastic products [1]	**I** HF-cable and handpieces	**J** Powertools
Preparation at the point of use	Deposition	Wet	+	+	+	+	-	+	+	+
		Dry	+	+	+	+	+	+	+	+
Decontamination	Preparation	Selection according to the Cleaning and Disinfection Procedures								
	Cleaning	Manual [3]	+	+	+	+	+	+	+	+
		Machine [3]	+	+	+	+	+	+	+	+
		Ultrasonic	+	-	-	+	N.A.	-	+	-
		Alkaline detergent	+	+	+	+	-[2]	+	+	-
		Acidic detergent	-	-	-	-	-[2]	+	+	-
		Neutral detergent	+	+	+	+	+	+	+	+
	Rinsing [3]									
	Disinfection	Chemical	+	+	+	+	+	+	+	+
		Thermal	+	+	-	+	+	+	+	+
	Drying	T_{max}								

Table A.1 — Examples of processes that might be applied (concluded)

Maintenance										
Sterilization		Moist heat (preferred method)	+	+	-	+	+	+	+	+
		Low temperature steam and fomaldehyde	+	+	+	+	-	+	+	-
		Ethylene oxide	+	+	+	+	-	+	+	-
		Dry heat	+				+			
		Liquid Steriliant	+	+	+	+	-	+	+	-
		Gas Plasma	+	+	+	+	+	+	+	+

[1] Rubber or latex (also combined), siliconelastomer, plastics, closed hollow bodies, thermolabile.

[2] Applies only for aluminium alloys.

[3] For final rinsing deionized water is recommended.

Key

\+ might be suitable

\- not suitable

N.A . not applicable

NOTE The matrix provides typical results. Results may vary significantly depending on variations in device construction, device materials, device design and variations in reprocessing method.

Table A.2 — Table: blank table to define suitable reprocessing procedures

Process			Medical device							
			A Reusable surgical instruments	**B** Endoscopes (thermostable)	**C** Endoscopes (thermolabile	**D** Instruments for use with endoscopes	**G** Reusable containers	**H** Elastic products [1)]	**I** HF-cable and handpieces	**J** Powertools
Preparation at the point of use	Deposition	Wet Dry								
Decontamination	Preparation	Selection according to the Cleaning and Disinfection Procedures								
	Cleaning	Manual [3)]								
		Machine [3)]								
		Ultrasonic								
		Alkaline detergent								
		Acidic detergent								
		Neutral detergent								
	Rinsing [3)]									
	Disinfection	Chemical								
		Thermal								
	Drying	T_{max}								

Table A.2 — Table: blank table to define suitable reprocessing procedures (concluded)

Maintenance										
Sterilization		Moist heat								
		(preferred method)								
		Low temperature steam and fomaldehyde								
		Ethylene oxide								
		Dry heat								
		Liquid Steriliant								
		Gas Plasma								

[1] Rubber or latex (also combined), siliconelastomer, plastics, closed hollow bodies, thermolabile.

[2] Applies only for aluminium alloys.

[3] For final rinsing deionized water is recommended.

Key

\+ might be suitable

\- not suitable

N.A. not applicable

Annex B
(informative)

An example of reprocessing instructions for reusable medical devices

Processors may process medical devices from various device manufacturers, so for the sake of clarity manufacturers should adopt a consistent presentation of instructions for processing.

Processing instructions may be presented in accordance with Figure B.1 to aid manufacturers in achieving a consistent presentation.

The manufacturer should ensure that all required information is included, that it will be readily understood and the prominence of the various elements of the information is appropriate to their importance.

The following template Figure B.1 and example Figure B2 provide formats that may be used by manufacturers to achieve such consistency and may be applicable for the majority of medical devices.

NOTE This template represents one suggested format. There may be a number of different formats for the information that may be more appropriate.

Manufacturer: <Manufacturer name> **Method :** <ref.> **Symbol:** <sym>

Device(s): <list by catalogue number and device description, or generic type>

WARNINGS	<warnings re inappropriate chemicals, parameters, points of particular attention>
Limitations on reprocessing	<the number of reprocessing cycles permitted or other indications of end of life

INSTRUCTIONS	
Point of use:	<instructions/cautions>
Preparation for decontamination:	<instructions/cautions>
Cleaning: Automated	<instructions/cautions. Include equipment/materials/parameters>
Cleaning: Manual	<instructions/cautions. Include equipment/materials/parameters>
Disinfection:	<instructions/cautions. Include equipment/materials/parameters>
Drying	<instructions/cautions. Include equipment/materials/parameters>
Maintenance, Inspection and Testing:	<instructions/cautions. Include equipment/materials/parameters>
Packaging:	<instructions/cautions. Include materials/methods>
Sterilization:	<instructions/cautions. Include equipment/materials/parameters>
Storage:	<instructions/cautions>

Additional Information:	<Any other information considered helpful>
Manufacturer contact:	<Contact information for further information>

The instructions provided above have been validated by the manufacturer of the medical device as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

Date issued: <date>

Figure B.1 — Template: Processing instructions (reusable medical devices)