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English Version

Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017)

Traitement de produits de soins de santé - Informations relatives au traitement des dispositifs médicaux à fournir par le fabricant du dispositif (ISO 17664:2017)

Aufbereitung von Produkten für die Gesundheitsfürsorge - Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten (ISO 17664:2017)

This European Standard was approved by CEN on 3 August 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

European foreword

This document (EN ISO 17664:2017) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17664:2004.

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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 14971	EN ISO 14971:2012	ISO 14971:2007

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17664:2017 has been approved by CEN as EN ISO 17664:2017 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.6h first and second paragraphs only	4,5,6,7	
13.6i	4,5,6,7	ER 13.6 i) is covered only for the sterilization of devices supplied non-sterile as a further treatment prior to use.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the products falling within the scope of this standard.

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 17664:2004), which has been technically revised. The scope has been increased to include medical devices requiring disinfection and/or sterilization prior to use.

Introduction

This document applies to manufacturers of those medical devices that are intended to be processed by the user or a third party to be made ready for use. This includes

— medical devices that are intended for reuse and require processing to take them from their state after clinical use to the state of being cleaned, disinfected and/or sterilized and ready for their next use, and

— single-use medical devices that are supplied non-sterile but are intended to be used in a clean, disinfected and/or sterile state and therefore will require processing prior to use.

Significant advances in technology and knowledge have resulted in the development of complex medical devices to support the delivery of healthcare to patients. These advances have led to medical devices being designed that are potentially more difficult to clean, disinfect and/or sterilize.

Cleaning, disinfecting and sterilizing technologies have also undergone significant change in the past decade, resulting in new systems and approaches that can be applied in the processing of medical devices. This has led to a greater appreciation of the need for validation of processing including cleaning, disinfection and/or sterilization in order to ensure that medical devices are effectively processed. These developments have led to the need to ensure that manufacturers of reusable medical devices provide adequate instructions that support the end users to undertake safe and effective processing of medical devices, utilizing the available equipment and processes.

A medical device requiring processing is supplied with detailed processing instructions in order to ensure that, when followed correctly, the risks of transmission of infectious agents are minimized. In addition, effective processing minimizes the risk of other adverse effects on medical devices.

Cleaning is an important step in rendering a used medical device safe for reuse. Failure to remove contaminants (e.g. blood, tissues, microorganisms, cleaning agents and lubricants) from both the inside and outside surfaces of medical devices could compromise any subsequent disinfection and/or sterilization process or the correct functioning of the medical device. Single-use medical devices provided by the medical device manufacturer for processing prior to use can also require cleaning prior to further processing.

After cleaning, other factors can affect the safe and effective use of a medical device. For example, procedures for inspection and functional testing might be necessary to ensure that a medical device does not pose a safety risk when used. Manufacturers of medical devices can assist users by providing instructions on how this inspection and testing should be performed.

Manufacturers of medical devices that are to be processed have a responsibility to ensure that the design of the medical devices facilitates achievement of effective processing. This includes consideration of commonly available validated processes; examples are shown in Annex A. This annex can be used as a guide to validate procedures.

Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

1 Scope

This document specifies requirements for the information to be provided by the medical device manufacturer for the processing of a medical device that requires cleaning followed by disinfection and/or sterilization to ensure that the device is safe and effective for its intended use.

This includes information for processing prior to use or reuse of the medical device. The provisions of this document are applicable to medical devices that are intended for invasive or other direct or indirect patient contact.

Processing instructions are not defined in this document. Rather, this document specifies requirements to assist manufacturers of medical devices in providing detailed processing instructions that consist of the following activities, where applicable:

a) initial treatment at the point of use;

b) preparation before cleaning;

c) cleaning;

d) disinfection;

e) drying;

f) inspection and maintenance;

g) packaging;

h) sterilization;

i) storage;

j) transportation.

This document excludes processing of the following:

— non-critical medical devices not intended for direct patient contact;

— textile devices used in patient draping systems or surgical clothing;

— medical devices specified by the manufacturer for single-use only and supplied ready for use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
cleaning
removal of contaminants to the extent necessary for further processing or for intended use

Note 1 to entry: Cleaning consists of the removal, usually with detergent and water, of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated process that prepares the items for safe handling and/or further processing.

3.2
disinfecting agent
physical or chemical agent that is able to reduce the number of viable microorganisms

3.3
disinfection
process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

3.4
manual cleaning
removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process

3.5
manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

[SOURCE: ISO 13485:2016, 3.10, modified - notes to entry not included]

3.6
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the *manufacturer* (3.5) to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11]

3.7
packaging system
combination of a *sterile barrier system* (3.15) and *protective packaging* (3.10)

3.8
processing
<preparation of *medical devices* (3.6)> activity to prepare a new or used healthcare product for its intended use

Note 1 to entry: For the purposes of this document, processing includes cleaning, disinfection and sterilization (if necessary and applicable).

Note 2 to entry: For the purposes of this document, a healthcare product refers to a medical device.

3.9
processor
<preparation of *medical devices* (3.6)> organization and/or individual with the responsibility for carrying out actions necessary to prepare a new or reusable healthcare product for its intended use

Note 1 to entry: For the purposes of this document, a healthcare product refers to a medical device.

3.10
protective packaging
configuration of materials designed to prevent damage to the *sterile barrier system* (3.15) and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11607-1:2006, 3.13]

3.11
reusable medical device
medical device (3.6) designated or intended by the *manufacturer* (3.5) as suitable for *processing* (3.8) and reuse

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single-use only.

3.12
service life
number of *processing* (3.8) cycles and/or life-time that a *medical device* (3.6) can be subjected to and remain suitable and safe for its intended use

3.13
single-use medical device
medical device (3.6) designated or intended by the *manufacturer* (3.5) for one-time use only

Note 1 to entry: A single-use medical device is not intended to be further processed and used again.

3.14
sterile
free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, 2.43]

3.15
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

3.16
sterility assurance level
SAL
probability of a single viable microorganism occurring on an item after *sterilization* (3.17), expressed as the negative exponent to the base 10

3.17
sterilization
process used to render product free from viable microorganisms

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

3.18
sterilizing agent
physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under defined conditions

3.19
terminal process
final step of *processing* (3.8) to render a *medical device* (3.6) safe and ready for its intended use

3.20
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: ISO 9000:2015, 3.8.13, modified — the notes to entry have been deleted.]

3.21
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: ISO 9000:2015, 3.8.12 modified — the notes to entry have been deleted.]

3.22
washer-disinfector
WD
equipment designed to clean and disinfect product

Note 1 to entry: See the ISO 15883 series.

4 Validation of the processes identified in the information provided by the medical device manufacturer

4.1 The medical device manufacturer shall validate each process that is identified in the information supplied with the medical device. Validation shall demonstrate that each process is suitable for processing of the medical device.

4.2 The medical device manufacturer shall have objective evidence available that validation of the processing procedures has been undertaken to confirm that the specific medical device will be clean, disinfected and/or sterilized when processed as directed.

NOTE 1 In addition to the duty of a manufacturer to demonstrate the validity of provided information, national authorities can require the final effectiveness of the process to be verified by the processor.

NOTE 2 National authorities can allow or require the use of an alternative process. In such cases they usually require validation of those processes by the processor.

4.3 If a manufacturer supplies a number of different medical devices that share common attributes, then validation studies may be performed as a product family. If this approach is taken, the medical device manufacturer shall demonstrate commonality between the different medical devices and the validation studies shall address the worst case attribute(s) of the product family.

NOTE See C.1.

5 Risk analysis

The medical device manufacturer shall undertake risk analysis to determine the content and detail of the information to be provided to the user. The risk management undertaken by the manufacturer of the medical device shall comply with ISO 14971.

NOTE 1 Some of the points relevant to processing that any risk analysis can require (but not limited to) are as follows:

— nature and design of the medical device;

— nature of the contamination on the medical device;

— intended use;

— life cycle of the medical device;

— foreseeable user error and misuse;

— user training;

— equipment required for processing;

— accessories and consumables required for processing;

— necessary maintenance of the medical device;

— post-market information;

— limitation on number of reuses;

— necessary warnings.

The points above can also be of benefit to those validating alternative processes in accordance with 4.2, Note 2.

NOTE 2 Annex C provides information on classification of medical devices which can assist with any risk analysis process.

6 Information to be provided by the medical device manufacturer

6.1 General

6.1.1 The information specified in this clause shall take into account the nature of the medical device and its intended use.

6.1.2 Where disinfection is the terminal process, the medical device manufacturer shall specify validated method(s) to reduce the risk of transmission of infectious agents to a level appropriate for the intended use of the medical device. Medical device manufacturers shall specify in their processing instructions any special techniques and accessories that will enable the processor to provide a medical device that is suitable for its intended use.

6.1.3 Where sterilization is the terminal process, the medical device manufacturer shall specify validated method(s) to achieve the required sterility assurance level. Medical device manufacturers shall specify in their processing instructions any specific requirements that will enable the processor to provide a medical device that is suitable for its intended use.

6.1.4 When providing processing instructions, medical device manufacturers shall be aware of

— available national and international standards and guidelines,

— the need for specific training, and

— the processing equipment commonly available to the processor.

NOTE Annex A and Annex C provide information on classification of medical devices which can assist with identifying the information required.

6.1.5 The equipment or materials required in the specified processes shall be identified by their generic names or specification. Trade names may be added in cases where generic names do not provide sufficient information (see D.2).

6.2 Processing instructions

6.2.1 At least one validated method shall be specified for each applicable stage of processing of the medical device. The method shall be relevant to the market in which the medical device is to be supplied.

NOTE Annex A provides information on the commonly used processes available.

6.2.2 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:

a) details of process steps;

b) a description of the equipment and/or accessories;

c) specifications for process parameters and their tolerances.

NOTE For an example of appropriate text see Annex B.

6.3 Limitations and restrictions on processing

6.3.1 If processing of a medical device in accordance with the medical device manufacturer's instructions is known to lead to degradation that might limit the service life of the medical device, e.g. functionality, biocompatibility or suitability for effective processing, then the medical device manufacturer shall provide such information regarding limitations and restrictions to the processor.

6.3.2 If the service life of the medical device is limited by the number of processing cycles or some other end of life indicator(s) this information shall also be provided.

NOTE For example, this information if applicable, can provide a method to monitor the actual number of processing cycles.

6.3.3 Where an incompatibility of the medical device with a substance(s) or processing condition(s) is known, this information shall be provided.

6.4 Initial treatment at the point of use

If treatment of a medical device at the point of use is required to ensure effective processing of that medical device, then the following information shall be provided, where applicable:

a) a description of initial treatment techniques;

b) any checks that need to be undertaken;

c) the time between medical device use, the initial treatment and/or the next step of the process;

d) a description of the support systems and/or containers for transportation;

e) a description of the transportation steps.

6.5 Preparation before cleaning

If preparation of a medical device is required prior to cleaning to ensure effective processing of that medical device, then the following information shall be provided, where applicable:

a) a description of the process for disassembly of the medical device;

b) a description of the process for medical device preparation;

c) a description of the testing procedures;

d) a description of the process pre-cleaning techniques;

e) accessories and tools required.

NOTE For detailed guidance see Annex A.

6.6 Cleaning

6.6.1 General

6.6.1.1 At least one validated automated cleaning method (which may include a validated manual cleaning method as part of the automated cleaning validation) shall be specified unless the medical device cannot withstand any such process, in which case a statement shall be provided which alerts the user to this issue.

6.6.1.2 A validated method of manual cleaning shall be specified if automated cleaning is not possible.

6.6.2 Automated cleaning

6.6.2.1 If the automated cleaning process recommends the use of a washer-disinfector meeting the requirements of the ISO 15883 series, the information regarding the automated process may be limited to those parameters that are specific for the medical device, such as specific load configuration, positioning, connection, accessories, process chemicals, pressures or temperature limit(s) and a statement confirming the recommendation to use a washer-disinfector complying with the ISO 15883 series.

6.6.2.2 If the specific cleaning requirements of the medical device do not allow a generic claim of compatibility with a washer-disinfector meeting the requirements of the ISO 15883 series, then the following information shall be included, where applicable:

a) a description of the process and processing parameters including any limits the medical device can withstand;

b) a description of the accessories required;

c) identification and concentration of chemicals required;

d) the contact time of any cleaning agents used;

NOTE 1 The medical device manufacturer's instructions for use can direct the processor to refer to the detergent manufacturer's instructions for use with reference to concentration, temperature and contact time.

NOTE 2 See 6.1.5.

e) the quality of water to be used;

f) techniques to be used for rinsing (including the need for rinsing between cleaning and subsequent steps where the process residues could interact adversely with the disinfecting agent or sterilizing agent);

g) if known, identification of any incompatibilities of cleaning agents with the medical device.

NOTE 3 Additional information complying with 6.6.2.2 can be provided when the requirements of 6.6.2.1 are met if the medical device manufacturer chooses to do so.

6.6.3 Manual cleaning

If a manual cleaning method is specified, the following information shall be included, where applicable:

a) a description of the manual method with step by step instructions and the sequence of each individual process step;

b) a description of the process and processing parameters including any limits the medical device can withstand;

c) a description of the accessories required;

d) identification and concentration of chemicals required;

e) the contact time of any cleaning agents used;

NOTE The medical device manufacturer's instructions for use can direct the processor to refer to the detergent manufacturer's instructions for use with reference to concentration, temperature and contact time.

f) the quality of water to be used;

g) techniques to be used for rinsing (including the need for rinsing between cleaning and subsequent steps where the process residues could interact adversely with the disinfecting agent or sterilizing agent);

h) if known, identification of any incompatibilities of cleaning agents with the medical device.

6.7 Disinfection

6.7.1 General

6.7.1.1 If the medical device is intended to be disinfected, at least one validated automated disinfection method shall be specified unless the medical device cannot withstand any such process, in which case a statement shall be provided which alerts the user to this issue.

6.7.1.2 If the medical device is intended to be disinfected, a validated method of manual disinfection shall be specified if automated disinfection is not possible.

NOTE Disinfection can be an intermediate or terminal process for medical devices.

6.7.2 Automated disinfection

6.7.2.1 If the automated disinfection process recommends the use of a washer-disinfector meeting the requirements of the ISO 15883 series, the information regarding the automated process may be limited to those parameters that are specific for the medical device, such as specific load configuration, positioning, connection, accessories, chemical (in the case of chemical or chemo-thermal disinfection), pressures or temperature limit(s) and a statement confirming the recommendation to use a washer-disinfector complying with the ISO 15883 series.

6.7.2.2 If the specific disinfection requirements of the medical device do not allow a generic claim of compatibility with a washer-disinfector meeting the requirements of the ISO 15883 series, then the following information shall be included, where applicable:

a) a description of the process and processing parameters including any limits the medical device can withstand;

b) a description of the accessories required for the disinfection process;

c) identification and concentration of any chemicals required for the disinfection process;

d) the contact time of any disinfecting agent used;

NOTE 1 The medical device manufacturer's instructions for use can direct the processor to refer to the disinfecting agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

e) the quality of water to be used;

f) techniques to be used for rinsing;

g) if known, identification of any incompatibilities of disinfecting agents with the medical device.

NOTE 2 Additional information complying with 6.7.2.2 can be provided when the requirements of 6.7.2.1 are met if the medical device manufacturer chooses to do so.

6.7.3 Manual disinfection

If a manual disinfection method is specified, the following information shall be included, where applicable:

a) a description of the manual method with step by step instructions and the sequence of each individual process step;

b) a description of the process and processing parameters including any limits the medical device can withstand;

c) a description of the accessories required for the disinfection process;

d) identification and concentration of any chemicals required for the disinfection process;

e) the contact time of any disinfecting agent used;

NOTE 1 The medical device manufacturer's instructions for use can direct the processor to refer to the disinfecting agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

f) the quality of water to be used;

g) techniques to be used for rinsing;

h) if known, identification of any incompatibilities of disinfecting agents with the medical device.

NOTE 2 Disinfection can be carried out concurrently with cleaning of the medical device.

NOTE 3 When using chemical disinfection, carry-over residue from the cleaning process can interact adversely with the disinfecting agent, hence the need for consideration of 6.6.2.2 f) and 6.6.3 g) in ensuring that any residues on the medical device are within the specified limits at the end of the process stages.

6.8 Drying

Where drying is necessary, at least one verified drying method shall be specified. If a drying method is specified, the following information shall be included, where applicable:

a) a description of the process and processing parameters including any limits the medical device can withstand;

b) a description of the accessories required for the drying process;

c) specifications of the drying agent to be used;

d) the techniques to be used and any special requirements to facilitate drying.

NOTE Drying can be achieved as part of an automated cleaning and disinfection process.

When admitting rinse aids, biocompatibility can be detracted.

6.9 Inspection and maintenance

Relevant information shall be provided if inspection, functionality testing, maintenance (including replacement of parts) or calibration of a medical device is required during or after processing to ensure proper function and safe use of that medical device. The following information shall be included, where applicable:

a) the method(s) and performance criteria for inspecting the device with particular attention to medical device functionality including its impact on patient safety and safe use;

b) the method to be used for adjustment and/or calibration of the medical device;

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

d) the instructions for re-assembly of the medical device;

e) a description of special tools to be used to maintain the medical device.

6.10 Packaging

If a method for packaging and containing the medical device during and/or after processing is required, it shall be stated and be compatible with:

a) the specific conditions identified in the other processing stages;

b) the medical device.

NOTE Packaging can influence the attainment of sterilization conditions. Guidance on packaging for specific processes is provided in ISO/TS 16775 and ISO 11607-1.

6.11 Sterilization

6.11.1 If the medical device is intended to be sterilized, at least one validated sterilization method shall be specified.

6.11.2 If the recommended sterilization process meets the requirements of an applicable international standard such as moist heat (ISO 17665 series), low temperature steam and formaldehyde (ISO 25424), ethylene oxide (ISO 11135) or dry heat (ISO 20857), the information regarding the process may be limited to those parameters that are specific for the medical device, such as specific load configuration, accessories, pressure, time or temperature limit(s) and a statement confirming the recommended process standard.

6.11.3 If the specific sterilization requirements of the medical device do not allow a generic claim of compatibility with the standards listed in 6.11.2 then the following information shall be included, where applicable:

a) a description of the techniques to be used;

b) the accessories required for sterilization of the medical device;

c) description of the process and any restrictions on processing conditions;

d) the identification and concentration of the sterilizing agent required for the sterilization process;

e) the identification of maximum values of contaminants in condensate from steam for sterilization methods such as moist heat and /or low temperature steam and formaldehyde sterilization;

f) the required temperature of the sterilizing agent;

g) the relative humidity required for the sterilization process;

h) the minimum holding or exposure time of the sterilizing agent;

i) pressure required for the sterilization process;

j) a description of post-sterilization techniques/activities;

k) for sterilization methods where the level of specificity in a) – j) is not available or applicable, provide the sterilizer manufacturer, model(s) and specific cycle(s) for which the medical device has been validated.

NOTE Additional information complying with 6.11.3 can be provided when the requirements of 6.11.2 are met if the medical device manufacturer chooses to do so.

6.12 Storage

Information shall be provided on any specific limitations on time or conditions of storage of the processed medical device prior to use, where applicable.

6.13 Transportation

6.13.1 Where applicable, information shall be provided on any special requirements for the movement of a medical device from one location to the other.

6.13.2 To prevent damage to the medical device during transit, the use of specific racks, trays or rigid containers may be recommended by the manufacturer.

NOTE Annex A contains further information regarding transportation to the point of use and off-site.

7 Presentation of the information

7.1 Processing instructions shall be provided. If these are available in electronic format, then printed format versions shall be available on request. Processing instructions shall contain the information required by Clause 6 as appropriate.

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

7.2 For those medical devices where processing instructions are not required to accompany the medical device, other means of communicating the information shall be used, such as user manuals, symbols (see ISO 15223-1 and ISO 7000) or wall charts, supplied separately or by electronic means.

Annex A
(informative)

Commonly utilized processing methods

A.1 Thorough cleaning prior to disinfection or sterilization is important. If a medical device is not clean then the disinfection or sterilization process might be compromised. Failure to process medical devices correctly and effectively can risk transmission of infectious agents. Similarly other effects can occur, for example, corrosion and/or failure of the medical device to function correctly.

A.2 Table A.1 is meant to assist the manufacturer of medical devices to identify methods of processing that can be considered for inclusion in the processing instructions provided.

It is a compilation of processing steps typically performed in a health care facility. It is organized by the stages of the process (e.g. preparation at point of use, cleaning) and then further identifies processing steps and then commonly used methods to achieve the objective of that step. These are provided to help guide the medical device manufacturer to identify appropriate methods and choose steps that are typically practised by their intended users.

A.3 This information also indicates what a processor can consider to be appropriate processing methods for certain medical device categories. As such it could be used as an input to the risk analysis required by this document (Clause 5) to determine the extent of warnings to avoid damaging or unsafe processing methods for a particular medical device.

A.4 It is the responsibility of the medical device manufacturer to identify and validate specific procedures for the particular medical device being considered.

NOTE Users of Table A.1 are permitted to produce copies of this table, notwithstanding the fact that ISO retains all other rights regarding the entirety of the document.

Table A.1 — Processing steps typically performed in a health care facility

Process	Process stage	Relevant aspect	Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions	Recommended step YES/NO/N/A
All	All	All	— If specific protection of the processing personnel is required, describe appropriate personal protective equipment	
Initial treatment at point of use (6.4)	Remove contamination	Remove gross soiling	— Wipe clean	
			— Rinse with water	
			— Flush channels	
			— Other	
	Prepare for transportation	Prevent organics from drying	— Place in container with specified soaking solution	
			— Require initial treatments	
		Containment for safe transportation	— Method(s) needed for protection of the medical device, environment and health care personnel (place in puncture proof container, use of tip guards, holders and brackets to secure items, specific containment or labelling requirements, etc.)	
			— Mode of transportation (any special carts, racks, or other delivery methods)	
Preparation before cleaning (6.5)	Preparation	Disassembly	— If disassembly is required, provide device specific disassembly instructions with pictures	
		Gross debris removal	— Use of shower or spray gun or other rinsing mechanism	
			— Any special tools or equipment, e.g. brushes	
		Testing procedures	— Leak testing of flexible endoscopes	
Cleaning (6.6)	Manual cleaning (6.6.3)	Accessories	— Brushes (specify type, brush dimensions, filament types, etc. where relevant)	
			— Spray gun or other flushing accessories (including any minimum and/or maximum pressure)	
			— Any required dimensions for sinks, sink configuration, etc.	
			— Other special accessories	
		Water	— Water quality	
			— Any maximum temperature the medical device can withstand	
			— Volume requirements	
		Process chemicals	— Type of process chemicals to use (alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water only, etc.)	
			— Any parameters that might be different to those recommended or not specified by the process chemical manufacturer	

Process	Process stage	Relevant aspect	Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions	Recommended step YES/NO/N/A
		Rinsing	— Any parameters that might be different to those recommended or not specified by the process chemical manufacturer such as methods for determining adequate rinsing (minimum volume of water, time, etc.)	
	Ultrasonic cleaning (6.6)	Process chemicals	— Whether detergent solution is to be used and if so, specify type	
		Time	— Duration of exposure of medical device to ultrasonic cleaning (if applicable)	
		Parameters	— Required processing conditions for example time, temperature, ultrasonic power density and frequency	
		Connectors	— Racks, connectors and load carriers	
	Automated cleaning (6.6.2.1)	Process chemicals	— Type of process chemicals to (alkaline, acidic, neutral pH, enzymatic solution, rinse aids)	
		Water	— Water quality	
			— Maximum temperature (if applicable) that medical device can withstand	
		Cycle parameters	— Cycle parameters (time, temperature or cycle type such as "instrument cycle" "basin cycle", etc.) for each stage, including any minimum and/or maximum permissible values	
		Connectors	— Racks, connectors and load carriers	
			— Lumen rack or dedicated washer-disinfector	
			— Basin rack	
			— Other	
Disinfection (6.7)	Liquid chemical	Automated or manual	— Compatible types of liquid chemicals that can be used (composition and active ingredient)	
			— Validated exposure time and temperature to liquid chemical	
			— Water quality for rinse and minimum volume for rinsing	
	Thermal	Automated only	— Maximum time and temperature that medical device can withstand	
			— Water quality for final rinse	
Drying (6.8)			— How the medical device should be dried (pressurized air at recommended maximum air pressure, manual wiping, heat, etc.)	
			— If wiping is advised, use low-linting wipes	
			— Maximum temperature the medical device can withstand	
Inspection and maintenance (6.9)			— Any requirements for ensuring functionality such as sharpening, lubrication, testing device function, testing sheath integrity	

Process	Process stage	Relevant aspect	Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions	Recommended step YES/NO/N/A
Packaging (6.10)	Reassembly		— Whether medical device is not to be re-assembled (or only partially reassembled) prior to sterilization	
			— Reassembly instructions with pictures and/or text	
	Packaging	Type of sterile barrier system (SBS) if a particular specification and/or configuration of SBS is required	— Sterilization wrap	
			— Preformed SBS	
			— Rigid reusable container	
		Other systems	— Endoscope vacuum package systems	
			— Endoscope transport containers with lids and/or disposable covers	
Sterilization (6.11)	Moist heat	Air removal process	— Where it is necessary for attainment of sterilizing conditions, air removal requirements such as pulse high and low points, pulse depth and number of pulses for which the medical device has been validated	
		Sterilization stage	— Critical parameters such as time and temperature for which sterilization of the medical device has been validated	
			— Other parameters and/or accessories that can be relevant to particular medical devices such as pressure and density/mass (See ISO/TS 17665-3)	
	Ethylene Oxide (EO)		— EO concentration, time, temperature, relative humidity, for which the medical device has been validated	
			— Required time and temperature for aeration (see ISO 10993-7)	
	Vaporized Hydrogen Peroxide (VHP)		— Cycle(s) and model/type of equipment for which the medical device has been validated	
			— Accessories required	
	Low temperature steam and Formaldehyde		— Formaldehyde concentration, time, temperature for which the medical device has been validated	
			— Required time and temperature for aeration	
	Other sterilization processes		— Sterilization process including cycle and conditions for which the medical device has been validated	
Storage (6.12)			— Special storage conditions (duration, temperature and relative humidity).	
Transportation (6.13)		Transportation to point of use	— Special instructions for transportation of the medical device for its intended use	
		Shipping to outside facility	— Special instructions for safe transportation of a medical device to an outside repair facility	

Process	Process stage	Relevant aspect	Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions	Recommended step YES/NO/N/A
			— Special processing instructions for compromised medical device to render the device safe for shipping and handling	
			— Method(s) needed for protection of the medical device, environment and personnel (place in puncture proof container, use of tip guards, holders and brackets to secure items, specific containment or labelling requirements, etc.)	

Annex B
(informative)

Example of processing instructions for reusable medical devices

NOTE 1 This annex is intended to be read in conjunction with Annex A.

NOTE 2 Users of Table B.1 are permitted to produce copies of this table, notwithstanding the fact that ISO retains all other rights regarding the entirety of the document.

B.1 Processors can process medical devices from various medical device manufacturers, so for clarity, manufacturers of medical devices should adopt a consistent presentation of processing instructions.

B.2 Processing instructions can be presented in accordance with Table B.1 to aid medical device manufacturers in achieving a consistent presentation.

B.3 The medical device manufacturer should ensure that all required information is included, that it will be easily understood and the prominence of the various elements of the information is appropriate to their importance.

B.4 Table B.1 provides a format that can be used by medical device manufacturers to achieve such consistency and should be applicable for the majority of medical devices.

NOTE This template represents a model format. There could be a number of different formats for the information. However, the subject headings could be encompassed in any alternative format.

B.5 Instructions should be clear, concise and comply with any national language regulations for the intended country of use.

B.6 Reference to materials and equipment should be generic, where possible.

B.7 Instructions and diagrams (where appropriate) for disassembly/assembly, maintenance and inspection/test can be documented separately (these instructions are more likely to be specific to a particular medical device, whereas other instructions are more likely to apply to a group or family of medical devices).

B.8 All sections of the table should include an entry. Phrases such as "no particular requirements", "not applicable", etc. can be used where appropriate.

B.9 The symbol field can be used to refer to the instructions from markings on the medical device or its packaging.

Table B.1 — Processing instructions (reusable medical devices)

Manufacturer: <Manufacturer name> **Method:** <ref.> **Symbol:** <sym> **Device(s):** <list by catalogue number and device description, or generic type>	
WARNINGS	<warnings re inappropriate process chemicals, parameters, points of particular attention>
Limitations on processing	<the number of processing cycles permitted or other indications of end of life>

INSTRUCTIONS	
Initial treatment at the point of use	<instructions/cautions>
Preparation before cleaning	<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 reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Date issued: <date>

Annex C
(informative)

Classification of medical devices

C.1 General

C.1.1 Following the scope of this document, a medical device can be classified in several ways. The most common methods are based either upon the potential for causing harm (such as the Spaulding classification) or its challenge to the process. Classifications devised from challenges to the process are usually based upon medical device design groupings. By classifying a medical device, manufacturers are better able to satisfy the requirements of Clauses 4, 5 and 6.

C.1.2 There are several standards and guidance documents that offer methodologies for classification of medical devices including ISO 15883-4, ISO/TS 17665-3, EN 16442, AAMI/TIR 12 and AAMI/TIR 30. Many of these documents adopt the concept of product families. This concept is particularly helpful at performance qualification stages of processing equipment installation but can also be of use to the medical device manufacturer in validating their processing instructions.

C.2 Spaulding classification

C.2.1 General

Spaulding (1957) proposed three categories of medical devices that are based on a device's potential for transmitting infections. This is a rational approach to disinfection and sterilization of patient-care items and equipment. Spaulding's classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. Other classification schemes are also used.

The classification of a medical device is dependent on the intended use of that medical device.

C.2.2 Non-critical items

Non-critical items come into contact with intact skin only or are devices not intended for direct patient contact.

EXAMPLE Blood pressure cuffs, bedpans, crutches and environmental surfaces.

C.2.3 Semi-critical items

Semi-critical items come into contact with mucous membranes or non-intact skin.

EXAMPLE Anaesthesia equipment, respiratory equipment.

C.2.4 Critical items

Critical items enter normally sterile parts of the human body.

EXAMPLE Surgical instruments, implants, invasive medical devices.

C.3 Medical device design groups for processing

C.3.1 Key principles

Device manufacturers should consider how the size, shape or configuration of the devices will allow the processor to clean, disinfect or sterilize the medical device. Materials used in the design of the device should be compatible with the recommended cleaning and disinfection process chemicals when used under the expected processing conditions. Understanding the factors that affect the success of the process is key. Clause 5 requires the manufacturer perform a risk analysis to determine the content and detail of the processing information to be provided. By grouping medical devices into classes or families this process can be managed better.

C.3.2 Design considerations

The following is a list of design features that should be considered, where applicable, as having an effect upon the ability of a cleaning, disinfection or sterilization process to succeed and hence the ease of processing:

— size (e.g. microsurgical instruments);

— weight;

— crevices;

— shift-shaft arrangements (e.g. Rongeurs);

— valves;

— fittings with close tolerances;

— lumens of flexible design;

— multiple internal lumens;

— lumens that are not easily accessible;

— clamps/joints that do not open fully for cleaning (e.g. pylorus clamps);

— small internal parts (e.g. springs, magnets);

— size of mated surfaces and covered gaps;

— rough and irregular surfaces;

— connecting parts (e.g. luer locks);

— porous materials;

— junctions between insulating sheaths and activating mechanisms;

— dead-ended/blind end chambers;

— powered instruments with motors and channels which can entrap debris;

— internal moving parts such as multiple control cables within sheaths;

— shrink tubing and coatings;

— materials that have limited process chemical compatibility, scratch easily or are prone to corrosion;

— tightly coiled metal shafts (e.g. coiled shafts on flexible endoscope forceps);

— heat sensitivity;

— pressure sensitivity.

Annex D
(informative)

Additional guidance on information to be provided by the medical device manufacturer

D.1 Evaluation of appropriate processing methods (see Clause 6)

The evaluation of appropriate processing methods is a task attributed to authorities (e.g. regulators, notified bodies, accrediting agencies). This evaluation includes the relevance of the processing methods to the market specific requirements. This independent evaluation certifies that processing documents for a device registered by the authorities fulfil the market specific requirements and laws regarding processing of reusable medical devices.

D.2 Generic information versus trade names (see 6.1.5)

D.2.1 Although some process chemical manufacturers use the same base active substance, these process chemicals often differ in the auxiliary agents or excipients, which might not be identified by name and are often commercial-in-confidence (proprietary).

D.2.2 The evaluation of the performance of some process chemicals, such as a cleaning agents, are not regulated by standards; medical device manufacturers validate their recommended processing method by using specific products and specific test methods. The medical device manufacturer's recommended processing instructions are the result of this specific validation process that demonstrates the medical device can be cleaned/disinfected and where required, sterilized when the defined process is followed. Processors are expected to understand that any change in product or parameter (e.g. concentration, temperature, pH value, water quality, techniques, contact time) can influence the outcome of the process.

Bibliography

[1] ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

[2] ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[3] ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

[4] ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

[5] ISO/TS 11139:2006, *Sterilization of health care products — Vocabulary*

[6] ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

[7] ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[8] ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

[9] ISO 15883 (all parts), *Washer-disinfectors*

[10] ISO/TS 16775, *Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2*

[11] ISO 17665 (all parts), *Sterilization of health care products — Moist heat*

[12] ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

[13] ISO 25424, *Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

[14] EN 16442, *Controlled environment storage cabinet for processed thermolabile endoscopes*

[15] AAMI/TIR 12, *Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*

[16] AAMI/TIR 30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*