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

Part 1: Critical and semi-critical medical devices

Traitement de produits de soins de santé — Informations relatives au traitement des dispositifs médicaux à fournir par le fabricant du dispositif —

Partie 1: Dispositifs médicaux critiques et semi-critiques

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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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 204, *Sterilization of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 17664-1 cancels and replaces ISO 17664:2017, of which it constitutes a minor revision. The changes to ISO 17664:2017 are as follows:

— the title, introduction and scope have been editorially revised to reflect the addition of a second part to the ISO 17664 series.

A list of all parts in the ISO 17664 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document applies to manufacturers of those medical devices that are intended to be cleaned, disinfected and/or sterilized by the processor 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 ready for their next use. This may include one or more of cleaning, disinfection and sterilization.

— Single-use medical devices that require processing before use and are intended to be used in a clean and/or disinfected and/or sterile state.

Significant advances in technology and knowledge have resulted in the development of complex medical devices to support the delivery of health care 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 medical devices provide adequate instructions that support 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 subsequent use. Failure to remove contaminants (e.g. blood, tissues, microorganisms, cleaning agents and lubricants) from the surfaces of a medical device could compromise the correct functioning of the medical device, its safe use and (if required) any subsequent disinfection process, sterilization process or both. 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 can 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, which 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 —

Part 1: Critical and semi-critical medical devices

1 Scope

This document specifies requirements for the information to be provided by the medical device manufacturer for the processing of critical or semi-critical medical devices (i.e. a medical device that enters normally sterile parts of the human body or a medical device that comes into contact with mucous membranes or non-intact skin) or medical devices that are intended to be sterilized.

This includes information for processing prior to use or reuse of the medical device.

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 unless they are intended to be sterilized;

— 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.

NOTE See ISO 17664-2:2021, Annex E, for further guidance on the application of the ISO 17664 series to a medical device.

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 https://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 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.

[SOURCE: ISO 11139:2018, 3.46, modified — Note 1 to entry has been added.]

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

[SOURCE: ISO 11139:2018, 3.159]

3.5
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *medical device manufacturer* (3.6) 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]

3.6
medical device 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 their name, whether or not such a medical device is designed and/or manufactured by that person or on their 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 11139:2018, 3.167, modified — Notes 1 to 7 to entry have been deleted and a new Note 1 to entry has been added.]

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

3.8
processing
<preparation of *medical devices* (3.5)> activity to prepare a new or used health care 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 health care product refers to a medical device.

3.9
processor
<preparation of *medical devices* (3.5)> organization and/or individual with the responsibility of carrying out actions necessary to prepare a new or reusable health care product for its intended use

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

[SOURCE: ISO 11139:2018, 3.216, modified — Note 1 to entry has been added.]

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 11607-1:2019, 3.14]

3.11
reusable medical device
medical device (3.5) designated or intended by the *medical device manufacturer* (3.6) 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.

[SOURCE: ISO 11139:2018, 3.236]

3.12
service life
number of *processing* (3.8) cycles and/or lifetime that a *medical device* (3.5) can be subjected to and remain suitable and safe for its intended use

3.13
single-use medical device
medical device (3.5) designated or intended by the *medical device manufacturer* (3.6) 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 11139:2018, 3.271]

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
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* (3.5) 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 11139:2018, 3.314, modified — Notes 1 and 2 to entry have been deleted.]

3.22
washer-disinfector
equipment designed to clean and disinfect product

Note 1 to entry: See the ISO 15883 series.

[SOURCE: ISO 11139:2018, 3.319, modified — abbreviated term WD removed and Note 1 to entry added.]

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 conform with ISO 14971.

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

— 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.

These points 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;

— 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 Annex D).

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, accessories or both;

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, for example 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, containers for transportation or both;

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 conforming 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 conforming 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 conforming 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 instructions 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 conforming 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 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;

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, calibration or both of the medical device;

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

d) the instructions for reassembly 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) a 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) the pressure required for the sterilization process;

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

For sterilization methods where the level of specificity in a) to 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 conforming 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 can 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.

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 (e.g. place in puncture-proof container, use of tip guards, holders and brackets to secure items, specific containment or labelling requirements)	
			— 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 (e.g. specify type, brush dimensions, filament types, where relevant)	
			— Spray gun or other flushing accessories (including any minimum and/or maximum pressure)	
			— Any required dimensions for sinks, sink configuration other required sink details.	
			— Other special accessories	
		Water	— Water quality	
			— Any maximum temperature the medical device can withstand	
			— Volume requirements	
		Process chemicals	— Type of process chemicals to use (e.g. alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water only)	
			— Any parameters that might be different to those recommended or not specified by the process chemical manufacturer	
		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 (e.g. minimum volume of water, time)	
	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, e.g. 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)	

Table A.1 *(continued)*

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
		Water	— Water quality	
			— Maximum temperature (if applicable) that medical device can withstand	
		Cycle parameters	— Cycle parameters (e.g. time, temperature or cycle type such as "instrument cycle", "basin cycle") 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 (e.g. pressurized air at recommended maximum air pressure, manual wiping, heat)	
			— 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	
Packaging (6.10)	Reassembly		— Whether medical device is not to be reassembled (or only partially reassembled) prior to sterilization	
			— Reassembly instructions with pictures, text or both	
	Packaging	Type of sterile barrier system (SBS) if a particular specification or configuration of SBS, or both, is required	— Sterilization wrap	
			— Preformed SBS	
			— Rigid reusable container	
		Other systems	— Endoscope vacuum package systems	
			— Endoscope transport containers with lids, disposable covers or both	
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, density or 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)	

Table A.1 *(continued)*

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
	Vaporized hydrogen peroxide (VHP)		— Cycle(s) and model or 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	
			— 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 (e.g. place in puncture-proof container, use of tip guards, holders and brackets to secure items, specific containment or labelling requirements)	

Annex B
(informative)

Example of processing instructions for reusable medical devices

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

B.1 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.2 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.3 Processing instructions can be presented in accordance with Table B.1 to aid medical device manufacturers in achieving a consistent presentation.

B.4 The medical device manufacturer should ensure that all required information is included, that it will be easily understood and that the prominence of the various elements of the information is appropriate to their importance.

B.5 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.6 Instructions should be clear and concise.

NOTE There might be national language regulations for the intended country of use.

B.7 Reference to materials and equipment should be generic, where possible.

B.8 Instructions and diagrams (where appropriate) for disassembly or assembly, maintenance and inspection or 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.9 All sections of the table should include an entry. Phrases such as “no particular requirements” or “not applicable” can be used where appropriate.

B.10 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>