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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 2: Non-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 2: Dispositifs médicaux non 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*.

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 non-critical medical devices that are intended to be cleaned and/or disinfected by the processor to be made ready for use or reuse. 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;

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

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 and/or disinfect.

Cleaning and disinfecting 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 and/or disinfection 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 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 subsequent use. Failure to remove contaminants (e.g. blood, tissues, microorganisms, cleaning agents and lubricants) from surfaces of medical devices could compromise the correct functioning of the medical device, its safe use and (if required) any subsequent disinfection process. 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 risk to safety 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 —

Part 2: Non-critical medical devices

1 Scope

This document specifies requirements for the information to be provided by the medical device manufacturer for the processing of non-critical medical devices not intended to be sterilized (i.e. a medical device that is intended to come into contact with intact skin only or a medical device not intended for direct patient contact).

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) preparation before processing;

b) cleaning;

c) disinfection;

d) drying;

e) inspection and maintenance;

f) packaging;

g) storage;

h) transportation.

This document excludes processing of:

1) critical and semi-critical medical devices;

2) medical devices intended to be sterilized;

3) textile medical devices used in patient draping systems or surgical clothing;

4) medical devices specified by the manufacturer for single use only and supplied ready for use.

NOTE See 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
cleaning agent
physical or chemical entity, or combination of entities, having activity to render an item clean

[SOURCE: ISO 11139:2018, 3.47]

3.3
clinical use
use of a health care product during a procedure on a patient

[SOURCE: ISO 11139:2018, 3.49]

3.4
disinfecting agent
physical or chemical agent used for disinfection

[SOURCE: ISO 11139:2018, 3.83]

3.5
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.6
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]

3.7
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar related article, intended by the manufacturer 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, but which may be assisted in its intended 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:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal tissues and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 11139:2018, 3.166]

3.8
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.]

3.9
process chemical
formulation of substances intended for use in equipment

[SOURCE: ISO 11139:2018, 3.207]

3.10
processing
<preparation of medical devices> activity to prepare a new or used 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, 3.214, modified — Note 1 to entry has been added.]

3.11
processor
<preparation of medical devices> 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.]

3.12
reusable medical device
medical device designated or intended by the manufacturer as suitable for processing 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]

3.13
service life
number of processing cycles and/or lifetime up to which a product is claimed to remain suitable and safe for its intended use when used according to the labelling

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

[SOURCE: ISO 11139:2018, 3.251, modified — Note 1 to entry has been added.]

3.14
single-use medical device
medical device labelled or intended to be used on one individual during a single procedure

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

[SOURCE: ISO 11139:2018, 3.255, modified — Note 1 to entry has been added.]

3.15
validation
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: ISO 11139:2018, 3.313, modified — Notes 1, 2 and 3 to entry have been deleted.]

3.16
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.]

3.17
washer-disinfector
WD
equipment designed to clean and disinfect product

Note 1 to entry: See the ISO 15883 series.

[SOURCE: ISO 11139:2018, 3.319, modified — Note 1 to entry has been added.]

4 Risk analysis

The medical device manufacturer shall undertake risk analysis to determine the content and detail of the information to be provided. 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 (but not limited to) include:

— the likely points of contact with the user and/or the patient that might allow cross-contamination;

— nature and design of the medical device;

— nature of the contamination on the medical device;

— intended use;

— 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;

— service life;

— necessary warnings.

The points above can also be of benefit to those validating alternative processes in accordance with the NOTE 2 to 5.2.

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

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

5.1 The medical device manufacturer shall validate each process that is identified in the information supplied with the medical device and demonstrate that each process is suitable for processing of the medical device. This shall include the intended points of contact with the user and/or the patient that could likely lead to cross-contamination. Parts of the medical device that are unlikely to lead to cross contamination may be excluded from validation, based upon the risk analysis described in Clause 4.

5.2 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 and/or disinfected, when processed as directed.

NOTE 1 A worst-case approach, representing those areas of the medical device that are the intended points of contact with the user, the patient or both and where there is opportunity for cross-contamination, can be used.

NOTE 2 In addition to the duty of a manufacturer to demonstrate the validity of provided information, national authorities can require the effectiveness of the final process to be verified by the processor.

NOTE 3 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.

5.3 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 For guidance on grouping of medical devices as product families, see C.1.

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, its intended location for use and processing and its intended use.

NOTE The location of processing can be at the point of use or within a processing department.

6.1.2 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.

6.1.3 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.

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

— available national and international standards and guidelines;

— if applicable, the need for specific training;

— the processing equipment commonly available to the processor.

NOTE 1 Some national standards and regulations require cleaning and disinfection for all non-critical medical devices.

NOTE 2 Annex A provides information which can assist with identifying the information required and the processing equipment commonly available.

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. Disinfection may be carried out concurrently with cleaning of the medical device.

NOTE 1 Annex A provides information on the commonly used processes available.

NOTE 2 The requirements for cleaning and disinfection are stated as separate clauses in this document. However, when the steps are concurrent, the requirements of both stages can be considered as one. In such cases removal of soil, a reduction in microorganisms and inactivation of viable microorganisms can be achieved as a result of the combination of applying the disinfecting agent and a physical action.

NOTE 3 The range of medical devices included within this document is wide and varied. Many of these medical devices (e.g. stethoscopes and blood pressure cuffs) are relatively simple medical devices which do not necessarily require automated processes. There will be other medical devices where automated processing is not possible or contra-indicated (e.g. some medical devices with electronic components). However, some medical devices such as beds, wheelchairs and footwear can be, and often are, subjected to automated processes. For this final group of medical devices, a validated method of automated processing can be specified and is preferred.

6.2.2 The method shall be appropriate to the market in which the medical device is to be supplied.

6.2.3 The following information shall be stated where it is required for 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, the accessories or both;

c) specifications for process parameters and, if applicable, their tolerances.

NOTE For an example of an appropriate format 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 can limit the service life of the medical device, 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.

6.3.3 Where an incompatibility of the medical device with a commonly used substance(s) or processing condition(s) that can impact upon patient safety is known, this information shall be provided.

6.4 Preparation before processing

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 and processing parameters for medical device preparation;

c) accessories and tools required.

NOTE For detailed guidance see Annex A.

6.5 Cleaning

6.5.1 General

At least one validated cleaning method shall be specified.

6.5.2 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 and, if applicable, any limits the medical device can withstand;

c) a description of the accessories required;

d) identification and concentration of process chemicals required;

e) the contact time of any cleaning agents used;

f) the quality of water to be used;

g) methods 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);

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

The medical device manufacturer's instructions for use may direct the processor to refer to the cleaning product manufacturer's instructions for use.

6.5.3 Automated cleaning

6.5.3.1 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, water quality, pressures or temperature limit(s) and a statement confirming the recommendation to use a washer-disinfector conforming with the ISO 15883 series.

6.5.3.2 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 process chemicals required;

d) the contact time of any cleaning agents used;

e) the quality of water to be used;

f) methods 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);

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

The medical device manufacturer's instructions for use may direct the processor to refer to the cleaning product manufacturer's instructions for use.

NOTE Additional information conforming with 6.5.3.2 can be provided when the requirements of 6.5.3.1 are met if the medical device manufacturer chooses to do so.

6.6 Disinfection

6.6.1 General

If disinfection is required, at least one validated disinfection method shall be specified.

NOTE When using chemical disinfection, carry-over residue from the cleaning process can interact adversely with the disinfecting agent.

6.6.2 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 and, if applicable, any limits the medical device can withstand;

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

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

e) the contact time of any disinfecting agent used;

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.

The medical device manufacturer's instructions for use may direct the processor to refer to the disinfectant manufacturer's instructions for use.

6.6.3 Automated disinfection

6.6.3.1 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 disinfection), water quality, pressures or temperature limit(s) and a statement confirming the recommendation to use a washer-disinfector conforming with the ISO 15883 series.

6.6.3.2 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 process chemicals required for the disinfection process;

d) the contact time of any disinfecting agent used;

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.

The medical device manufacturer's instructions for use may direct the processor to refer to the disinfectant manufacturer's instructions for use.

NOTE Additional information conforming with 6.6.3.2 can be provided when the requirements of 6.6.3.1 are met if the medical device manufacturer chooses to do so.

6.7 Drying

Where drying is necessary, at least one 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 and, if applicable, 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 methods to be used and any special requirements to facilitate drying.

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

6.8 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 reassembly of the medical device;

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

6.9 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 any subsequent processing stages;

b) the medical device;

c) environmental conditions during storage, transport or both.

6.10 Storage

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

6.11 Transportation

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

NOTE 1 To prevent damage to the medical device during transport, the use of specific carts, containers, covers and other accessories can be recommended by the manufacturer.

NOTE 2 Annex A contains further information regarding transportation to the point of use and off site.

7 Presentation of the information

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

NOTE 2 ISO 20417 provides guidance on the format and presentation of instructions for use.

Annex A
(informative)

Commonly utilized processing methods

A.1 Thorough cleaning prior to disinfection is important. If a medical device is not clean, the disinfection 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. 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 medical device manufacturer can consider to be used as an input to the risk analysis required by this document (Clause 4) 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.

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 medical device specific protection of the processing personnel is required, describe appropriate personal protective equipment	
Preparation before processing (6.4)	Preparation	Disassembly	— If disassembly is required, provide medical-device-specific disassembly instructions	
			— Any special tools or equipment	
Cleaning (6.5)	Manual cleaning (wipe systems) (6.5.2)	Accessories	— Wipes (specify type, non-linting, etc.)	
		Process chemicals	— Type of process chemicals to use	
			— Application method and parameters, including any that may be different to those recommended or not specified by the process chemical manufacturer	
	Manual cleaning (immersive) (6.5.2)	Accessories	— Wipes, brushes and other cleaning implements (specify type, dimensions, non-linting, etc.)	

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	
			— 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, water only)	
			— Application parameters, including any that are different to those recommended or not specified by the process chemical manufacturer	
		Rinsing	— Any parameters that may 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)	
	Automated cleaning (6.5.3.1)	Process chemicals	— Type of process chemicals to use (alkaline, acidic, neutral pH, enzymatic solution, rinse aids)	
		Water	— Water quality	
			— Maximum temperature that medical device can withstand	
		Cycle parameters if not recommending the use of a washer-disinfector in accordance with the ISO 15883 series (see 6.5.3.1)	— Cycle parameters (time, temperature or cycle type) for each stage, including any minimum and/or maximum permissible values	
		Connectors	— Product specific racks, connectors, adaptors and load carriers	
Disinfection (6.6)	Manual disinfection (wipe systems) (6.6.2)	Accessories	— Wipes (specify type, non-linting, etc.)	
		Process chemicals	— Type of process chemicals to use	
			— Application method and parameters, including any that may be different to those recommended or not specified by the process chemical manufacturer	
		Rinse method	— Water quality for rinse and minimum volume for rinsing	

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
	Manual disinfection (immersion systems) (6.6.2)	Accessories	— Syringes and other equipment (specify type, dimensions, etc.)	
		Process chemicals	— Types of process chemicals to use (e.g. disinfectant type)	
			— Parameters, including any that are different to those recommended or not specified by the process chemical manufacturer	
		Water	— Water quality for rinse and minimum volume for rinsing	
			— Any maximum temperature the medical device can withstand	
		Rinse method	— Parameters, including any that may be different to those recommended or not specified by the process chemical manufacturer	
	Automated chemical disinfection (6.6.3)	Process chemicals	— Type of process chemicals to use (e.g. disinfectant type)	
			— Parameters, including any that are different to those recommended or not specified by the process chemical manufacturer	
		Water	— Water quality	
			— Maximum temperature that medical device can withstand	
		Cycle parameters if not recommending the use of a washer-disinfector in accordance with the ISO 15883 series (see 6.6.3.1)	— Cycle or cycle parameters, and type of equipment for which the medical device has been validated	
		Connectors	— Product specific racks, connectors, adaptors and load carriers	
	Automated Thermal disinfection (6.6.3)	Water	— Water quality	
			— Maximum temperature that medical device can withstand	
		Cycle parameters if not recommending the use of a washer-disinfector in accordance with the ISO 15883 series (see 6.6.3.1)	— Cycle or cycle parameters, and type of equipment for which the medical device has been validated	
		Connectors	— Product specific racks, connectors, adaptors and load carriers	
	Automated other disinfection systems (6.6.3)	Cycle parameters	— Cycle or cycle parameters, and type of equipment for which the medical device has been validated	

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
Drying (6.7)			— Drying method (e.g. drying cabinet, pressurized air, manual wiping, heat)	
			— If wiping is advised, use low-linting wipes	
			— Maximum temperature the medical device can withstand	
Inspection and maintenance (6.8)			— Any requirements for testing and ensuring functionality	
			— Action to be taken if functionality is compromised	
			— Accessories that can be required to assist with inspection (lighted magnification)	
		Reassembly	— Reassembly instructions	
Packaging (6.9)			— Vacuum package systems	
			— Containers with lids, disposable covers or both, carts or other items to protect from environmental conditions	
Storage (6.10)			— Storage conditions (duration, temperature and relative humidity)	
			— Equipment necessary for storage	
Transportation (6.11)		Transport to point of use	— Instructions for transport of the medical device	
		Shipping to outside facility	— Instructions for safe transport of a medical device to an outside repair facility	
			— 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. holders and brackets to secure items, specific containment or labelling requirements)	

Annex B
(informative)

Example processing instructions for non-critical reusable medical devices

NOTE Annex B provides additional guidance to compliment the guidance in Annex A.

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 understood and the prominence of the various elements of the information is appropriate to their importance. IEC 62366-1 can apply to processing instructions.

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 and concise.

NOTE There might be 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 assembly or disassembly, maintenance and inspection or testing 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 or be deleted from the table. Phrases such as “no particular requirements” or “not applicable” 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 (non-critical reusable medical devices)

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

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

Warnings	<Warnings regarding inappropriate process chemicals, parameters, points of particular attention>
Limitations on processing	<The number of processing cycles permitted or other indications of service life>

Instructions	
Preparation before cleaning	<Instructions/cautions>
Cleaning	<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>
Storage	<Instructions/cautions>
Additional information	<Any other information considered helpful>
Manufacturer contact	<Contact information for further information>

These instructions 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)

Processing classification and grouping of medical devices

C.1 General

C.1.1 Following the scope of the ISO 17664 series, a medical device's processing classification can be considered in several ways. The method for assessing the potential for transmission of infectious material to the patient is based on the Spaulding classification. In addition, this document establishes a grouping with respect to the challenge to the process.

C.1.2 For the purposes of this document, the classification of a medical device refers to the processing aspect of the medical device only and is dependent on the intended use of that medical device. For example, infusion pumps are critical from a functional perspective because the patient's life can depend on them, but for processing the external surfaces only they could be classified as non-critical.

C.1.3 Groupings devised from challenges to the process are usually based upon medical device design features. By classifying and/or grouping a medical device, manufacturers are better able to satisfy the requirements of Clauses 4, 5 and 6.

C.2 The Spaulding classification

C.2.1 General

Spaulding proposed three categories of medical devices that are based on a medical 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, mattresses, monitors and incubators.

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

C.3.1.1 Device manufacturers should consider how the size, shape or configuration of the devices will allow the processor to clean or disinfect 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 4 requires the manufacturer to 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.3.1.2 There are several standards and guidance documents that offer methodologies for grouping of medical devices, including ISO 15883-4, ISO/TS 17665-3, EN 16442, AAMI TIR12 and AAMI TIR30. 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.3.2 Medical device design features

Design features should be evaluated with a focus on the intended points of contact (see 5.1). The following is a list of design features that should be considered, where applicable, as having an effect upon the ability of a cleaning or disinfection process to succeed and hence the ease of processing:

— crevices;

— fittings with close tolerances;

— lumens;

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

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

— size of mated surfaces and covered gaps;

— rough and irregular surfaces;

— connecting parts (e.g. cables);

— porous materials;

— dead-end or blind-end chambers;

— medical devices with motors;

— shrink tubing and coatings;

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

— heat sensitivity;

— pressure sensitivity;

— electronic components and processors.

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).

NOTE ASTM D8179-18 identifies published consensus test methods that cleaning agent manufacturers can use.

D.2.2 The evaluation of the performance of some process chemicals, such as 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 and, where required, disinfected 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.