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

Traitement de produits de soins de santé — Informations devant être fournies par le fabricant de l’appareil pour le traitement des dispositifs médicaux

ICS: 11.080.01
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.

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

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

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.

ISO 17664 was prepared by Technical Committee ISO/TC 198, Sterilization of health care products.

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

This International Standard applies to manufacturers of those medical devices that are intended to be processed by the user or a third party to be made ready for use. This includes medical devices that are intended for reuse and require processing to take them from their state after clinical use to the state of being cleaned, disinfected and/or sterilized and ready for their next use. This also includes some single-use medical devices that are supplied non-sterile but are intended to be used in a clean, disinfected and/or sterile state and therefore will require processing prior to use.

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

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

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

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

After cleaning, other factors can affect the safe and effective use of a medical device. For example, procedures for inspection and functional testing are necessary to ensure that a medical device does not pose a safety risk when used. Manufacturers of medical devices can assist end 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. Others may use this annex to validate their own procedures.
Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

1 Scope

1.1 Inclusions

This International Standard specifies requirements for the information to be provided by the medical device manufacturer for the processing of a medical device that requires cleaning followed by disinfection and/or sterilization to ensure that the device is safe and effective for its intended use. This includes information for processing prior to use or reuse of the medical device. The provisions of this standard are applicable to medical devices that are intended for invasive or other direct or indirect patient contact. Processing instructions are not defined in this standard. Rather, this International Standard specifies requirements to assist manufacturers of medical devices in providing detailed processing instructions that consist of the following activities where applicable:

a) Pre-treatment at the point of use before processing;
b) Preparation before cleaning;
c) Cleaning;
d) Disinfection;
e) Drying;
f) Inspection, maintenance and functionality testing;
g) Packaging;
h) Sterilization;
i) Storage;
j) Transportation.

1.2 Exclusions

This standard excludes:

a) Noncritical medical devices not intended for direct patient contact;
b) Textile devices used in patient draping systems or surgical clothing;
c) Processing of medical devices specified by the manufacturer for single-use only and supplied sterile.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
3 Terms and definitions

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

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

[SOURCE CD ISO 11139]

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

3.2 disinfection
process to remove, destroy, or deactivate microorganisms on surfaces of product to a level previously specified for its intended use

[SOURCE CD ISO 11139]

3.3 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 e.g. washer-disinfector
3.4 **manufacturer**
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

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 14971:2007, definition 2.8]

3.5 **medical device**
instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific 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 for medical purposes by means of in vitro examination of specimens derived from the human body;

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


3.6 **objective evidence**
data supporting the existence or verity of something

Note 1 to entry: Objective evidence may be obtained through observation, measurement, test (3.8.3), or other means.


3.7 **packaging system**
combination of a sterile barrier system and protective packaging

[SOURCE CD ISO 11139]

3.8 **processing**
activity including cleaning, disinfection and sterilization (if necessary and applicable), to prepare a new or used healthcare product for its intended use

Note 1 to entry: In the use of this standard, a healthcare product refers to a medical device.

[SOURCE CD ISO 11139]
3.9 processor
organization and/or individual with the responsibility for carrying out the actions necessary to prepare a new or reusable healthcare product for its intended use

Note 1 to entry: In the use of this standard, a healthcare product refers to a medical device.

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

[SOURCE CD ISO 11139]

3.11 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 CD ISO 11139]

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

3.13 Single-use medical device
medical device designated or intended by the manufacturer for one-time use only

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

[SOURCE CD ISO 11139]

3.14 sterile
free from viable microorganisms


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


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

Note 1 to entry: The term SAL takes a quantitative value, generally $10^{-3}$ or $10^{-6}$. When applying this quantitative value to assurance of sterility, an SAL of $10^{-6}$ has a lower value but provides a greater assurance of sterility than an SAL of $10^{-3}$.

[SOURCE CD ISO 11139]
3.17  
**sterilization**  
validated 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  

**[SOURCE: ISO/TS 11139:2006, definition 2.50]**

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

3.20  
**validation**  
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications  


3.21  
**verification**  
provision of objective evidence, that a given item fulfils specified requirements  

**[SOURCE: VIM 2008]**

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

Note 1 to entry: This does not include those machines designed specifically to wash linen or clothing. Additionally, machines intended to sterilize or be designated as sterilizers are detailed in other standards.

**[SOURCE CD ISO 11139]**

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 to ensure the device is suitable for its intended purposes.

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 sterilised 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 ISO 17665 Part 3 provides information on assigning product families for steam sterilization. ISO 15883 Part 4 provides information on assigning product families for processing of endoscopes in a washer-disinfector. EN 16442 provides information on assigning product families for storage and/or drying of endoscopes in a controlled environment storage cabinet. Annex C also provides information on classification of medical devices.

5 Risk analysis

5.1 General

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 comply with ISO 14971.

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

— nature and design of 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 medical device;
— foreseeable misuse;
— post-market information;
— limitation on number of reuses;
— necessary warnings.

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

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 Clause 6 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 C provides information on classification of medical devices which can assist with identifying the information required.

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

6.2 Processing instructions

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

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

6.2.2 The following information shall be stated where it is critical to the maintenance of the intended function of the medical device and the safety of the user(s) and the patient:
   a) details of process steps;
   b) a description of the equipment and/or accessories;
   c) specifications for process parameters and their tolerances.

NOTE For an example of appropriate text see Annex B.

6.3 Limitations and restrictions on processing

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

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

NOTE If the manufacturer specifies the number of processing cycles that a medical device can be subjected to, it is recommended that a method be provided 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, a suitable statement shall be provided.

6.4 Pre-treatment at the point of use before processing

6.4.1 If pre-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 pre-treatment techniques;
b) any checks that need to be undertaken;
c) critical time that can elapse between use of the medical device and the pre-treatment;
d) a description of the support systems and/or containers for transportation;
e) a description of the transportation steps.

6.5 Preparation before cleaning

6.5.1 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) requirements for disassembly of the medical device;
b) requirements for device preparation;
c) testing procedures;
d) pre-cleaning techniques;
e) accessories and tools required.

NOTE For detailed guidance please 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 pre-cleaning 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.

6.6.1.2 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 ISO 15883, the information regarding the automated process may be limited to those parameters that are specific for the medical device, such as specific load configuration, accessories, process chemicals, pressures or temperature limit(s) and a statement confirming the recommendation to use a washer–disinfector complying with ISO 15883.

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 ISO 15883 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;

   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.

d) the quality of water to be used;

e) 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 disinfectant or sterilant).

   NOTE Additional information complying with 6.6.2.2 can still 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;

   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.

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 disinfectant or sterilant).

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

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

e) the quality of water to be used;

f) techniques to be used for rinsing;

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

NOTE Additional information complying with 6.7.2.2 can still 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 disinfectant used;

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

f) the quality of water to be used;

g) techniques to be used for rinsing;

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

NOTE In certain circumstances disinfection can be carried out concurrently with cleaning of the medical device. When using chemical disinfection, carry-over residue from the cleaning process can interact adversely with the disinfectant, hence the need for consideration of 6.6.2.2 e) and 6.6.3 f) 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.

6.9 Inspection, maintenance and functionality testing

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

a) the method(s) and performance criteria for inspecting the device with particular attention to medical device functionality including its impact on patient safety and safe use;
b) the method to be used for adjustment and/or calibration of the medical device;
c) the type, amount and method of application of lubricant;
d) the instructions for re-assembly of the medical device;
e) a description of special tools to be used to maintain the medical device.

6.10 Packaging

If a specific method for packaging and containing the medical device during and/or after processing is required, it shall be stated and be compatible with the specific conditions identified in the recommended process and the medical device.

NOTE Packaging can influence the attainment of sterilization conditions; Guidance on packaging for specific processes is provided in ISO 17665-1, 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), low temperature steam and formaldehyde (ISO 25424), ethylene oxide (ISO 11135) or dry heat (ISO 20857), the information regarding the process may be limited to those parameters that are specific for the medical device, such as specific load configuration, accessories, pressure, time or temperature limit(s) and a statement confirming the recommended process standard.

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

a) a description of the techniques to be used;
b) the accessories required for sterilization of the medical device;
c) description of the process and any restrictions on processing conditions;
d) the identification and concentration of the sterilant required for the sterilization process;
e) the identification of maximum values of contaminants in condensate from steam for sterilization methods such as moist heat, ethylene oxide and/or steam and formaldehyde sterilization;
f) the required temperature of the sterilizing agent;
g) the humidity required for the sterilization process;
h) the minimum holding or exposure time of sterilant;
i) pressure required for the sterilization process;
j) a description of post-sterilization techniques/activities.

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

6.11.4 Wherever possible:

a) moist heat (steam) sterilization shall be recommended;
b) where moist heat sterilization is recommended, the medical device manufacturer shall include instructions to use a steam sterilization process that is capable of meeting the requirements of the steam penetration tests described in ISO 17665-2.

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 original manufacturers.

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 and ISO 7000) or wall charts, supplied separately or by electronic means.
Annex A
(informative)

Commonly utilized processing methods

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

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

It is a compilation of processing steps typically performed in the sterile processing area of 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 assume 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 standard (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.
### Table A.1 — Processing steps typically performed in the sterile processing area of a health care facility

<table>
<thead>
<tr>
<th>Process</th>
<th>Process Stage</th>
<th>Relevant Aspect</th>
<th>Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions</th>
<th>Indicate if a recommended step YES / NO / N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>All</td>
<td>• All</td>
<td>• If specific protection of the processing personnel is required, describe appropriate personal protective equipment</td>
<td></td>
</tr>
</tbody>
</table>
| Pre-treatment at point of use before processing (6.4.1) | 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  
  • Use appropriate pre-treatments  
  • Containment for safe transportation  
  • Method(s) needed for protection of the medical device, environment and health care personnel (place in puncture proof container, use of tip guards, holders and brackets to secure items, specific containment or labelling requirements etc.)  
  • Mode of transportation (any special carts, racks, or other delivery methods) |                                            |
| Preparation before cleaning (6.5) | Preparation | • Disassembly | • If disassembly is required, provide device specific disassembly instructions with pictures  
  • Gross debris removal  
  • Use of shower or spray gun or other rinsing mechanism  
  • Any special tools or equipment e.g. brushes  
  • Testing Procedures  
  • Leak testing of flexible endoscopes |                                            |
### Table A.1 (continued)

<table>
<thead>
<tr>
<th>Process</th>
<th>Process Stage</th>
<th>Relevant Aspect</th>
<th>Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions</th>
<th>Indicate if a recommended step YES / NO / N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cleaning</strong> (6.6)</td>
<td>Manual cleaning (6.6.3)</td>
<td><strong>Accessories</strong></td>
<td>• Brushes (specify type, brush dimensions, filament types etc. where relevant)</td>
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<td>• Spray gun or other flushing accessories (including any minimum and/or maximum pressure)</td>
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<td>• Any required dimensions for sinks, sink configuration, etc.</td>
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<td>• Other special accessories</td>
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<td><strong>Water</strong></td>
<td>• Water quality</td>
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<td></td>
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<td>• Any maximum temperature the medical device can withstand</td>
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<td>• Volume requirements</td>
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<tr>
<td></td>
<td></td>
<td><strong>Process chemicals</strong></td>
<td>• Type of process chemicals to use (alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water only etc.)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Any special parameters that may be different to those recommended or not specified by the process chemical manufacturer</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Rinsing</strong></td>
<td>• Any special parameters that may be different to those recommended or not specified by the process chemical manufacturer such as methods for determining adequate rinsing (minimum volume of water, time, etc.)</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasonic cleaning</strong> (6.6.2.1)</td>
<td></td>
<td><strong>Process chemicals</strong></td>
<td>• Whether detergent solution is to be used and if so, specify type</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Time</strong></td>
<td>• Duration of exposure of medical device to ultrasonic cleaning (if applicable)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Parameters</strong></td>
<td>• Required processing conditions for example time, temperature, ultrasonic power density and frequency</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Connectors</strong></td>
<td>• Racks, connectors and load carriers</td>
<td></td>
</tr>
</tbody>
</table>
### Table A.1 (continued)

<table>
<thead>
<tr>
<th>Process</th>
<th>Process Stage</th>
<th>Relevant Aspect</th>
<th>Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions</th>
<th>Indicate if a recommended step YES / NO / N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated cleaning (6.6.2.1)</td>
<td>• Process chemicals</td>
<td>• Type of process chemicals to (alkaline, acidic, neutral pH, enzymatic solution, rinse aids)</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td>• Water</td>
<td>• Water quality</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td>• Maximum temperature (if applicable) that medical device can withstand</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Cycle parameters</td>
<td>• Cycle parameters (time, temperature or cycle type such as “instrument cycle” “basin cycle” etc.) for each stage, including any minimum and/or maximum permissible values</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td>• Connectors</td>
<td>• Racks, connectors and load carriers</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td>• Lumen rack or dedicated washer-disinfector</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Basin rack</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Other</td>
<td><img src="image" alt="Examples" /></td>
<td><img src="image" alt="Indicate if" /></td>
<td></td>
</tr>
<tr>
<td>Disinfection (6.7)</td>
<td>Liquid chemical</td>
<td>• Automated or manual</td>
<td>• Compatible liquid chemicals that can be used</td>
<td><img src="image" alt="Examples" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Validated exposure time to liquid chemical</td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Water quality for rinse and minimum volume for rinsing</td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td>Thermal</td>
<td>• Automated only</td>
<td>• Maximum time and temperature that medical device can withstand</td>
<td><img src="image" alt="Examples" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Water quality for final rinse</td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td>Drying (6.8)</td>
<td></td>
<td></td>
<td>• How the medical device should be dried (pressurized air at recommended maximum air pressure, manual wiping, heat, etc.)</td>
<td><img src="image" alt="Examples" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• If wiping is advised, use low-linting wipes</td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Maximum temperature the medical device can withstand</td>
<td><img src="image" alt="Indicate if" /></td>
</tr>
<tr>
<td>Inspection, maintenance and functionality testing (6.9)</td>
<td></td>
<td></td>
<td>• Any requirements for ensuring functionality such as sharpening, lubrication, testing device function, testing sheath integrity</td>
<td><img src="image" alt="Examples" /></td>
</tr>
</tbody>
</table>
### Table A.1 (continued)

<table>
<thead>
<tr>
<th>Process</th>
<th>Process Stage</th>
<th>Relevant Aspect</th>
<th>Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions</th>
<th>Indicate if a recommended step YES / NO / N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Packaging</strong> (6.10)</td>
<td>Reassembly</td>
<td></td>
<td>• Whether device is not to be reassembled (or only partially reassembled) prior to sterilization</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Device-specific reassembly instructions with pictures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Packaging</td>
<td></td>
<td>• Sterilization wrap</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Preformed SBS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Rigid reusable container</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Other systems</td>
<td>• Endoscope vacuum package systems</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Endoscope transport containers with lids and/or disposable covers</td>
<td></td>
</tr>
<tr>
<td><strong>Sterilization</strong> (6.11)</td>
<td>Moist heat</td>
<td>• Air removal process</td>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sterilization stage</td>
<td>• Critical parameters such as time and temperature for which sterilization of the medical device has been validated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Other parameters and/or accessories that may be relevant to particular medical devices such as pressure and density/mass (See ISO/TS 17665-3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethylene Oxide (EO)</td>
<td></td>
<td>• EO concentration, time, temperature, relative humidity, for which the medical device has been validated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Required time and temperature for aeration (see ISO 10993-7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaporised Hydrogen Peroxide (VHP)</td>
<td></td>
<td>• Cycle(s) and model/type of equipment for which the medical device has been validated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Accessories required</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low temperature steam and Formaldehyde</td>
<td></td>
<td>• Formaldehyde concentration, time, temperature for which the medical device has been validated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Required time and temperature for aeration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other sterilization processes</td>
<td></td>
<td>• Sterilization process including cycle and conditions for which the medical device has been validated</td>
<td></td>
</tr>
<tr>
<td><strong>Storage</strong> (6.12)</td>
<td></td>
<td></td>
<td>• Special storage conditions including duration, temperature and humidity.</td>
<td></td>
</tr>
</tbody>
</table>
Table A.1 (continued)

<table>
<thead>
<tr>
<th>Process</th>
<th>Process Stage</th>
<th>Relevant Aspect</th>
<th>Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions</th>
<th>Indicate if a recommended step YES / NO / N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportation (6.13)</td>
<td>• Transportation to point of use</td>
<td>• Special instructions for transportation of the medical device for its intended use</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Shipping to outside facility</td>
<td>• Special instructions for safe transportation of a medical device to an outside repair facility</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Special processing instructions for compromised medical device to render the device safe for shipping and handling</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Method(s) needed for protection of the medical device, environment and personnel (place in puncture proof container, use of tip guards, holders and brackets to secure items, specific containment or labelling requirements etc.)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex B  
(informative)

An example of processing instructions for reusable medical devices

NOTE  Annex A should be read in conjunction with this Annex B.

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 Figure B.1 to aid medical device manufacturers in achieving a consistent presentation.

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

B.4 The following template Figure B.1 and example Figure B.2 provide formats 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 the recommended format. There could be a number of different formats for the information. However the subject headings should be encompassed in other formats.

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

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

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

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

B.9 The symbol field is optional, it can be used to refer to the instructions from markings on the medical device or its packaging.
**Figure 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>

<table>
<thead>
<tr>
<th>Task</th>
<th>Instructions/Cautions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WARNINGS</strong></td>
<td>&lt;warnings re inappropriate process chemicals, parameters, points of particular attention&gt;</td>
</tr>
<tr>
<td>Limitations on processing</td>
<td>&lt;the number of processing cycles permitted or other indications of end of life&gt;</td>
</tr>
<tr>
<td><strong>INSTRUCTIONS</strong></td>
<td></td>
</tr>
<tr>
<td>Pre-treatment at the point of use:</td>
<td>&lt;instructions/cautions&gt;</td>
</tr>
<tr>
<td>Preparation before cleaning:</td>
<td>&lt;instructions/cautions&gt;</td>
</tr>
<tr>
<td>Cleaning: Automated</td>
<td>&lt;instructions/cautions. Include equipment/materials/parameters&gt;</td>
</tr>
<tr>
<td>Cleaning: Manual</td>
<td>&lt;instructions/cautions. Include equipment/materials/parameters&gt;</td>
</tr>
<tr>
<td>Disinfection:</td>
<td>&lt;instructions/cautions. Include equipment/materials/parameters&gt;</td>
</tr>
<tr>
<td>Drying:</td>
<td>&lt;instructions/cautions, include equipment/materials/parameters&gt;</td>
</tr>
<tr>
<td>Maintenance, Inspection and Testing:</td>
<td>&lt;instructions/cautions. Include equipment/materials/parameters&gt;</td>
</tr>
<tr>
<td>Packaging:</td>
<td>&lt;instructions/cautions. Include materials/methods&gt;</td>
</tr>
<tr>
<td>Sterilization:</td>
<td>&lt;instructions/cautions. Include equipment/materials/parameters&gt;</td>
</tr>
<tr>
<td>Storage:</td>
<td>&lt;instructions/cautions&gt;</td>
</tr>
<tr>
<td>Additional Information:</td>
<td>&lt;Any other information considered helpful&gt;</td>
</tr>
<tr>
<td>Manufacturer contact:</td>
<td>&lt;Contact information for further information&gt;</td>
</tr>
</tbody>
</table>

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the 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>
Figure B.2 — Example

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

Device(s): All reusable surgical instruments supplied by <Suppliers Name> comprising fixed assemblies (no moving parts) and simple hinged assemblies, excluding those containing aluminium alloy.

NOTE Aluminium alloy might be recognized by bright coloured (red, blue, green, yellow) coatings on metallic components.

| WARNINGS | Aluminium based instruments are damaged by alkaline (pH>7) process chemicals. Long narrow cannulations and blind ends require particular attention during cleaning. Do not exceed yy°C |
| Limitations on processing | Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. |

| INSTRUCTIONS |
| Pre-treatment at the point of use: | Remove gross soil with disposable low–linting cloth/paper wipe. |
| Containment and transportation: | No particular requirements. It is recommended that these instruments are processed as soon as is reasonably practical following use. |
| Preparation before cleaning: | No particular requirements. Disassembly not required. |
| Cleaning: Automated | Equipment: Washer-disinfector, process chemical (name)  1 Load the instruments such that hinges are open and cannulations and blind ends can drain.  2 Run cycle, minimum xx minutes wash and xx minutes rinse.  3 When unloading check cannulations, blind ends etc. for complete removal of visible soil. If necessary repeat cycle or use manual cleaning. |
### Cleaning: Manual

Equipment: Neutral Detergent, brush, running water method

1. Rinse gross soil from instrument.
2. Using brush, apply detergent solution to all surfaces ensuring that hinged instruments are cleaned in both open and closed positions.

**NOTE** Clean cannulations and blind ends using a soft bristled, 3.2 mm diameter brush ensuring that full depth of the feature is reached.

3. Rinse using water for 5 minutes. Ensure that water passes through cannulations, and that blind ends are repeatedly filled and emptied.

### Disinfection:

Disinfectant solution A (name) should be used in accordance with label instructions.

Alternatively disinfectant solution B (name) can also be used in accordance with label instructions.

If automated cleaning is employed, a final rinse at $yy\,^\circ\,C$ for $xx$ minutes can be used to effect thermal disinfection.

### Drying:

When drying is achieved as part of a washer-disinfector cycle do not exceed $120\,^\circ\,C$.

### Maintenance:

Apply a small quantity of surgical grade lubrication oil to hinges. Discard blunt or damaged instruments.

### Inspection and Function Testing:

Hinged instruments: Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action.

All instruments: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge.

Check instruments with long slender features (particularly rotating instruments) for distortion. Where instruments form part of a larger assembly, check assembly with mating components.

### Packaging:

A standard sterile barrier system may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.

In sets: Instruments may be loaded into dedicated instrument trays, or general-purpose sterilization trays. Ensure that cutting edges are protected, and do not exceed $z$ Kg per tray. Wrap the trays using appropriate method.

### Sterilization:

Vacuum steam sterilize, minimum of $x$ minutes at $y\,^\circ\,C$. Do not exceed $y\,^\circ\,C$.

### Storage:

No particular requirements.

### Additional Information:

When sterilising reusable instruments in one autoclave cycle ensure that the sterilizer’s maximum load is not exceeded.

### Manufacturer contact:

See brochure for telephone and address of local representative or telephone (44) 123 456 789.

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the 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.
Annex C
(informative)

Classification of medical devices

C.1 General

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

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

C.2 The Spaulding Classification

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

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

C.2.1 Noncritical items

Noncritical items come into contact with intact skin only.

Noncritical items are divided into noncritical patient-care items and noncritical environmental surfaces.

EXAMPLE 1 Noncritical patient-care items: bedpans, blood pressure cuffs, and crutches.
EXAMPLE 2 Noncritical environmental surfaces: hospital bed, electrical equipment.

C.2.2 Semicritical items

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

EXAMPLE Anaesthesia equipment, Respiratory equipment.

C.2.3 Critical items

Critical items enter normally sterile parts of the human body.

EXAMPLE Surgical instruments, implants, invasive devices.
C.3 Medical device design groups for processing

C.3.1 Key principles

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

C.3.2 Design Considerations

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

- size (e.g. microsurgical instruments);
- weight;
- crevices;
- shift-shaft arrangements (e.g. Rongeurs);
- valves;
- fittings with close tolerances;
- lumens of flexible design;
- multiple internal lumens;
- lumens that are not easily accessible;
- clamps/joints that do not open fully for cleaning (e.g. pylorus clamps);
- small internal parts (e.g. springs, magnets);
- size of mated surfaces and covered gaps;
- rough and irregular surfaces;
- connecting parts (e.g. luer locks);
- porous materials;
- junctions between insulating sheaths and activating mechanisms;
- dead-ended/blind end chambers;
- powered instruments with motors and channels which can entrap debris;
- internal moving parts such as multiple control cables within sheaths;
- shrink tubing and coatings;
- materials that have limited process chemical compatibility, scratch easily or are prone to corrosion;
— tightly coiled metal shafts (e.g. coiled shafts on flexible endoscope forceps);
— heat sensitivity;
— pressure sensitivity.
Annex D
(informative)

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

D.1 Evaluation of appropriate processing methods (see 6.0)

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 The majority of process chemical manufacturers use the same base active substance. These process chemicals often only differ in the auxiliary agents or excipients, which might not be identified by name and are often commercial-in-confidence (proprietary). The evaluation of the performance of a process chemical, such as a cleaning agent, is not regulated by standards.

D.2.2 Medical device manufacturers validate their recommended processing method by using specific products and specific test methods. The medical device manufacturer’s recommended processing instructions are the result of this specific validation process that demonstrates the medical device can be cleaned/disinfected and where required, sterilized when the defined process is followed. Processors are expected to understand that any change in product, trade name or parameter (e.g. concentration, temperature, pH value, water quality, techniques, contact time) can influence the outcome of the process.
Annex ZA
(informative)

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

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Clauses of this EN</th>
<th>Essential Requirements (ERs) of Directive 93/42/EEC</th>
<th>Qualifying remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,5,6,7</td>
<td>13.6h</td>
<td>The third paragraph of 13.6h referring to providing information on known characteristics and technical factors of medical devices indicated for single use is not addressed by this standard.</td>
</tr>
<tr>
<td>4,5,6,7</td>
<td>13.6i</td>
<td>Paragraph 13.6i is addressed by this standard with respect to those devices supplied non-sterile but require sterilization prior to use.</td>
</tr>
</tbody>
</table>

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

WARNING 2 Other Union legislation may be applicable to the products falling within the scope of this standard.
Convenors Note for DIS: These documents are included in the bibliography because they are referred to within the standard. This will be reviewed further.

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


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

[5] ISO 15223, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied - Part 2: Symbol development, selection and validation*


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

