INTERNATIONAL STANDARD

ISO 17664

Second edition
2017-10

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 relatives au traitement des dispositifs médicaux à fournir par le fabricant du dispositif

Reference number
ISO 17664:2017(E)

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

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

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

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Introduction

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

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

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

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

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

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

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

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

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

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

1 Scope

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

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

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

a) initial treatment at the point of use;

b) preparation before cleaning;

c) cleaning;

d) disinfection;

e) drying;

f) inspection and maintenance;

g) packaging;

h) sterilization;

i) storage;

j) transportation.

This document excludes processing of the following:

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

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

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

2 Normative references

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

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

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3 Terms and definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

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

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

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

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

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

[SOURCE: ISO 13485:2016, 3.11]

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

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

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

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

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

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

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

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

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

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

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

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

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

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3.14
sterile
free from viable microorganisms

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

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

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

3.17
sterilization
process used to render product free from viable microorganisms

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

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

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

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

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

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

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

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

Note 1 to entry: See the ISO 15883 series.

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