INTERNATIONAL STANDARD

ISO 17664-1

First edition
2021-07

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

Part 1: Critical and semi-critical medical devices

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

Partie 1: Dispositifs médicaux critiques et semi-critiques

Reference number
ISO 17664-1:2021(E)

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Published in Switzerland

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Foreword

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

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

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

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

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

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

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

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

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

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

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Introduction

This document applies to manufacturers of those medical devices that are intended to be cleaned, disinfected and/or sterilized by the processor to be made ready for use. This includes:

— Medical devices that are intended for reuse and require processing to take them from their state after clinical use to the state of being ready for their next use. This may include one or more of cleaning, disinfection and sterilization.

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

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

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

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

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

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

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

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

Part 1: Critical and semi-critical medical devices

1 Scope

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

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

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

a) initial treatment at the point of use;

b) preparation before cleaning;

c) cleaning;

d) disinfection;

e) drying;

f) inspection and maintenance;

g) packaging;

h) sterilization;

i) storage;

j) transportation.

This document excludes processing of the following:

— non-critical medical devices unless they are intended to be sterilized;

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

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

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

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2 Normative references

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

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

3 Terms and definitions

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

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

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

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

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

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

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

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

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

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

[SOURCE: ISO 11139:2018, 3.159]

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

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

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

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

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

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

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

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

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11]

3.6
medical device manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name, whether or not such a medical device is designed and/or manufactured by that person or on their behalf by another person(s)

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

[SOURCE: ISO 11139:2018, 3.167, modified — Notes 1 to 7 to entry have been deleted and a new Note 1 to entry has been added.]

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

3.8
processing
<preparation of *medical devices* (3.5)> activity to prepare a new or used health care product for its intended use

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

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

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

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

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

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

[SOURCE: ISO 11607-1:2019, 3.14]

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

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

[SOURCE: ISO 11139:2018, 3.236]

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

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

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

3.14
sterile
free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

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

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

3.17
sterilization
process used to render product free from viable microorganisms

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

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

3.19
terminal process
final step of *processing* (3.8) to render a *medical device* (3.5) safe and ready for its intended use

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

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

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

[SOURCE: ISO 11139:2018, 3.314, modified — Notes 1 and 2 to entry have been deleted.]

3.22
washer-disinfector
equipment designed to clean and disinfect product

Note 1 to entry: See the ISO 15883 series.

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

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

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

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

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

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

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

NOTE See C.1.

5 Risk analysis

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

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

— nature and design of the medical device;

— nature of the contamination on the medical device;

— intended use;

— life cycle of the medical device;

— foreseeable user error and misuse;

— user training;

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