INTERNATIONAL STANDARD

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

Part 1: Critical and semi-critical medical devices

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

Partie 1: Dispositifs médicaux critiques et semi-critiques

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Foreword

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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

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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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