
**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

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).

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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.

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.

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.