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Irish Standard
I.S. EN ISO 17664-1:2021

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 (ISO 17664-1:2021)

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National Foreword

I.S. EN ISO 17664-1:2021 is the adopted Irish version of the European Document EN ISO 17664-1:2021, 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 (ISO 17664-1:2021)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17664-1

September 2021

ICS 11.080.01

Supersedes EN ISO 17664:2017

English Version

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 (ISO 17664-1:2021)

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 (ISO 17664-1:2021)

Aufbereitung von Produkten für die Gesundheitsfürsorge - Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten - Teil 1: Kritische und semi-kritische Medizinprodukte (ISO 17664-1:2021)

This European Standard was approved by CEN on 28 June 2021.

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European foreword

This document (EN ISO 17664-1:2021) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17664:2017.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

This document is an adoption of an International Standard. The definitions in applicable regulatory requirements differ from nation to nation and region to region. As a result, the definitions in this document can differ in wording from those in European Regulations. For use in support of European requirements, definitions in the European regulations for medical devices take precedence. For relationship with EU Directive(s) and Regulations, see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

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Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 14971	EN ISO 14971:2019	ISO 14971:2019

NOTE 2 The standards normatively referred to by EN ISO 17664 Part 2:2019 are undated. These referred standards also include normative references to other dated and undated standards. For undated normative references, it should always be assumed that the latest edition applies.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17664-1:2021 has been approved by CEN as EN ISO 17664-1:2021 without any modification.

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Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, 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 General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

This document is an adoption of an International Standard. The definitions in applicable regulatory requirements differ from nation to nation and region to region. As a result, the definitions in this document can differ in wording from those in European Regulations. For use in support of European requirements, definitions in the European regulations for medical devices take precedence.

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 Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

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 a General Safety and Performance 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 Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
23.4.i	4, 5, 6, 7	23.4.i is covered only for the disinfection, or sterilization of devices to make ready for first use.
23.4.m	4, 5, 6, 7	
23.4.n	4, 5, 6, 7	

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WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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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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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).

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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.

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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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