

**Nadomešča:****SIST EN ISO 14160:2011**

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**Sterilizacija medicinskih pripomočkov - Tekoča kemijska sredstva za sterilizacijo medicinskih pripomočkov za enkratno uporabo, ki uporabljajo živalska tkiva in njihove derivate - Zahteve za določitev lastnosti, razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO 14160:2020)**

Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)

Sterilisation von Produkten für die Gesundheitsfürsorge - Flüssige chemische Sterilisierungsmittel für Medizinprodukte für den einmaligen Gebrauch, bei denen tierische Gewebe und deren Derivate verwendet werden - Anforderungen an die Charakterisierung, Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 14160:2020)

Stérilisation des produits de santé - Agents stérilisants chimiques liquides pour dispositifs médicaux non réutilisables utilisant des tissus animaux et leurs dérivés - Exigences pour la caractérisation, le développement, la validation et le contrôle de routine d'un procédé de stérilisation de dispositifs médicaux (ISO 14160:2020)

**Ta slovenski standard je istoveten z: EN ISO 14160:2021**

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11.080.20      Dezinfektanti in antiseptiki      Disinfectants and antiseptics

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EUROPEAN STANDARD

EN ISO 14160

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

**Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)**

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This European Standard was approved by CEN on 24 December 2018.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO 14160:2021) 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 December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

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 14160:2011.

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

For the relationship with EU Directive(s) 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 latest edition of the referenced document (including any amendments) 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.

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When an IEC or ISO standard is referred to in the ISO standard text, this shall 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.

**Table — Correlation between undated 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 10012	EN ISO 10012:2003	ISO 10012:2003
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-17	EN ISO 10993-17:2009	ISO 10993-17:2002
ISO 11737-1	EN ISO 11737-1:2018	ISO 11737-1:2018
ISO 13408-7	EN ISO 13408-7:2015	ISO 13408-7:2015
ISO 13485	EN ISO 13485:2016	ISO 13485:2016
ISO 22442-2	EN ISO 22442-2:2015	ISO 22442-2:2015

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NOTE 2 Many of the standards normatively referred to by ISO 14160 are undated. These referred standards also include normative references themselves to other dated and undated standards. For undated normative references, it should always be assumed that the latest edition applies. For example, EN ISO 14160 refers to ISO 10993-1 which itself normatively refers to ISO 14971. In Europe, it should be presumed that the reference to ISO 14971 is to EN ISO 14971:2012.

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**Endorsement notice**

The text of ISO 14160:2020 has been approved by CEN as EN ISO 14160:2021 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 standardization request to provide one voluntary means of conforming to General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [O] 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.

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 [O] L 117]**

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives, including requirements that the medical device is safe and performs as intended after treatment. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial

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		<p>state other than sterility.</p> <p>This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of a specific microbial state using liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives are not covered.</p>
11.4 first sentence only	4,5,6,7,8,9,10,11,12	<p>This standard provides requirements for the development, validation and routine control of a sterilization process using liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives, including requirements that the medical device is safe and performs as intended after treatment.</p> <p>This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility using liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives are not covered. Evidence that the integrity of the packaging is maintained to the point of use is not covered.</p>
11.5	4,5,6,7,8,9,10,11,12	<p>This standard provides requirements for the development, validation and routine control of a sterilization process for medical devices using liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives.</p> <p>This relevant General Safety and Performance Requirement is only partly addressed in this European</p>

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		Standard. Packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility using liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives are not covered.
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**WARNING 1** — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

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

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**Sterilization of health care products —  
Liquid chemical sterilizing agents for  
single-use medical devices utilizing  
animal tissues and their derivatives  
— Requirements for characterization,  
development, validation and routine  
control of a sterilization process for  
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*Stérilisation des produits de santé — Agents stérilisants chimiques  
liquides pour dispositifs médicaux non réutilisables utilisant des tissus  
animaux et leurs dérivés — Exigences pour la caractérisation, le  
développement, la validation et le contrôle de routine d'un procédé de  
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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](http://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](http://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](http://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 third edition cancels and replaces the second edition (ISO 14160:2011), which has been technically revised.

The main changes compared to the previous edition are as follows:

- aligned definitions with those used in other standards for development, validation and routine control of sterilization processes and added new definitions;
- incorporated defined terms consistently throughout the document;
- updated cross-references;
- revised informative [Annex A](#) to follow the order of the normative body of the standard;
- added clarification to normative [Annex B](#) in regard to applying the overkill approach.

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](http://www.iso.org/members.html).

## Introduction

A sterile medical device is one that is free of viable microorganisms. International standards which specify requirements for validation and routine control of sterilization processes require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see for example, ISO 13485) have microorganisms on them prior to sterilization, albeit in low numbers. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism survives regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one medical device in a population of items subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a medical device.

Attention also has to be given to a number of factors, including the microbiological status (bioburden) of incoming raw materials and/or components and their subsequent storage, and to the control of the environment in which the product is manufactured, assembled and packaged (see also ISO 13485).

Requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognize that for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely, and the equipment is maintained.

Animal tissues and their derivatives are used as constituents of certain medical devices to provide performance characteristics that present advantages over the characteristics provided by non-animal-based materials. The range and quantities of materials of animal origin in medical devices vary; such materials can comprise a major part of the device, can be a product coating or impregnation, or can be used in the manufacturing process for the medical device.

This document describes requirements that, if met, will provide a liquid chemical sterilization process that has appropriate microbicidal activity for single-use medical devices containing materials of animal origin or their derivatives. The sterilizing agents used most frequently for medical devices are moist heat, dry heat, irradiation and ethylene oxide. While some devices containing animal tissues can be compatible with these commonly applied methods of sterilization (historically, for example, catgut sutures have been sterilized by irradiation), other devices, such as biological heart valves or tissue patches, are not compatible with conventional sterilization processes. It has been recognized that other sterilizing agents could have to be used in these exceptional circumstances. Liquid chemical sterilization is normally chosen over other sterilization processes in order that the medical devices present the desired physical properties of the tissue after sterilization. Sterilization by liquid chemicals of medical devices made in whole or in part from tissues of animal origin represents a special case in terms of establishing an effective sterilization process. In common with the other sterilization methods, the efficacy of a liquid chemical sterilization process needs to be demonstrated and recorded before it is adopted for routine use.

Liquid chemical sterilization requires determination of types of microorganisms comprising the bioburden and their resistance to the sterilization process in order to establish the appropriate reference microorganism, whether that be a recognized biological indicator or an isolate from the bioburden. Compliance with the requirements of this document ensures that the microbicidal activity of the liquid chemical sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable