SLOVENSKI STANDARD
oSIST prEN 556-1:2023

01-marec-2023

Sterilizacija medicinskih pripomočkov - Zahteve za medicinske pripomočke, ki morajo biti označeni s "STERILNO" - 1. del: Zahteve za končno sterilizirane medicinske pripomočke

Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

Sterilisation von Medizinprodukten - Anforderungen an Medizinprodukte, die als "STERIL" gekennzeichnet werden - Teil 1: Anforderungen an Medizinprodukte, die in der Endpackung sterilisiert wurden

Stérilisation des dispositifs médicaux - Exigences relatives aux dispositifs médicaux en vue d'obtenir l'étiquetage « STÉRILE » - Partie 1 : Exigences relatives aux dispositifs médicaux stérilisés de façon terminale

Ta slovenski standard je istoveten z: **prEN 556-1**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

oSIST prEN 556-1:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 556-1

January 2023

ICS 11.080.01

Will supersede EN 556-1:2001

English Version

Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

Stérilisation des dispositifs médicaux - Exigences relatives aux dispositifs médicaux en vue d'obtenir l'étiquetage " STÉRILE " - Partie 1 : Exigences relatives aux dispositifs médicaux stérilisés de façon terminale

Sterilisation von Medizinprodukten - Anforderungen an Medizinprodukte, die als "STERIL" gekennzeichnet werden - Teil 1: Anforderungen an Medizinprodukte, die in der Endpackung sterilisiert wurden

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 204.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Türkiye and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Contents

Page

European foreword

This document (prEN 556-1:2023) has been prepared by Technical Committee CEN/TC 204, Sterilization of medical devices, the secretariat of which is held by BSI.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 556-1:2001 and EN 556-1:2001/AC:2006.

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 relationship with EU Directive(s) / Regulation(s), see informative Annexes ZA and ZB, which is an integral part of this document.

EN 556, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE"*, is currently composed with the following parts:

— *Part 1: Requirements for terminally sterilized medical devices* [this document];

— *Part 2: Requirements for aseptically processed medical devices.*

prEN 556-1:2023 includes the following significant technical changes with respect to EN 556-1:2001 and EN 556-1:2001/AC:2006:

— definitions have been aligned with EN ISO 11139;

— the normative reference has been updated to the latest edition;

— informative Annex ZA has been replaced with informative Annexes ZA and ZB giving the relationship with the European Regulations for medical devices and *in vitro* diagnostic medical devices respectively;

— The Bibliography has been updated.

For any use of this document within the meaning of Annex ZA or ZB, 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.

Introduction

A sterile product item is one, which is free of viable microorganisms. European standards for *medical devices* require, when it is necessary to supply a *sterile* product item, that adventitious microbiological contamination of a medical device from all sources is minimized by all practical means. Even so, product items produced under standard manufacturing conditions in accordance with their requirements for quality systems for medical devices (see EN ISO 13485:2016 and EN ISO 13485:2016/A11:2021) can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such product items are non-sterile. The purpose of sterilization processing is to inactivate the microbiological contaminants and thereby transform the non-sterile items into sterile ones.

The inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize *medical devices* often approximates to an exponential relationship; inevitably this means that, regardless of the extent of treatment applied, there is always a finite probability that a microorganism will survive. 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 item subjected to sterilization processing cannot be guaranteed and the sterility of the processed items has to be defined in terms of the probability of the existence of a surviving microorganism on/in an item. The standards for quality management systems recognize that there are processes used which cannot be fully verified by subsequent inspection and testing of product. Sterilization is an example of such a process. Sterilization processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained.

It is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with the provision of assurance that the product item is *sterile* and, in this respect, suitable for its intended use. Attention has also to be given to a number of factors including the microbiological status (*bioburden*) of incoming raw materials and/or components, their subsequent storage and to the control of the environment in which the product is manufactured, assembled and packaged.

1 Scope

This document specifies the requirements for a terminally sterilized medical device to be designated 'STERILE'. Part 2 of this European standard specifies the requirements for an aseptically processed medical device to be designated "STERILE".

NOTE For the purpose of the EU Directive(s) for medical devices (see Bibliography), designation of a medical device as 'STERILE' is only permissible when a validated sterilization process has been applied. Requirements for validation and routine control of processes for the sterilization of medical devices are specified in EN ISO 11135, EN ISO 11137, EN ISO 14160, EN ISO 14937, EN ISO 17665-1, EN ISO 20857, EN ISO 25424 and ISO 22441.

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.

EN ISO 13485:2016,[1] *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)*

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:

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

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

3.1
bioburden
population of viable microorganisms on or in a product and/or sterile barrier system

[Source: EN ISO 11139:2018, 3.23]

3.2
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or software material, or other similar or related article, intended by the manufacturer 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;

[1] As impacted by EN ISO 13485:2016/A11:2021.

— disinfection of medical devices;

— 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, but which may be assisted in its intended 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:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[Source: EN ISO 13485:2016 and EN ISO 13485:2016/A11:2021, 3.11, modified — The first two list items in Note 1 to entry have been added.]

3.3
sterility
state of being free from viable micro-organisms

[Source: EN ISO 11139:2018, 3.274]

3.4
sterile
condition of a *medical device* that is free from viable micro-organisms

[Source: EN ISO 11139:2018, 3.271]

3.5
sterility assurance level
SAL
probability of a single viable microorganism occurring on an item after sterilization

Note 1 to entry: It is expressed as the negative exponent to the base 10.

[Source: EN ISO 11139:2018, 3.275]

3.6
terminally sterilized
condition of a product that has been exposed to a sterilization process in its sterilized barrier system

[Source EN ISO 11139:2018, 3.296]

4 Requirements

4.1 For a terminally sterilized medical device to be designated "STERILE", the probability of there being a viable micro-organism present on/in the device shall be equal to or less than 1×10^{-6}.

NOTE 1 Permission for acceptance of a probability greater than that specified in 4.1 may be sought through the appropriate regulatory bodies. Such permission requires consideration of the individual situation, including consideration of the risk management process (see, for example, EN ISO 14971) undertaken by the manufacturer of the medical device.

NOTE 2 ISO/TS 19930 provides guidance on identifying the aspects to be considered as part of a risk-based approach to selecting a sterility assurance level (SAL) for terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a SAL of 10^{-6}.

4.2 Compliance shall be shown by the manufacturer or supplier through provision of documentation and records which demonstrate that the devices have been subjected to a validated sterilization process fulfilling 4.1.

The documentation and records shall be retained as specified in EN ISO 13485:2016 and EN ISO 13485:2016/A11:2021, 4.2.4 and 4.2.5.

NOTE 1 Evidence that a medical device is sterile comes from: i) the initial validation of the sterilization process and subsequent revalidations that demonstrate the acceptability of the process; and ii) information gathered during routine control and monitoring which demonstrates that the validated process has been delivered in practice.

NOTE 2 The achievement of sterility is predicted from the bioburden level on products, the resistance of the microorganisms comprising that bioburden and the extent of treatment imposed during sterilization.

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 M/575 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] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

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.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail. In this context, the definition of 'medical device' in EN 556-1 is a modified version of the definition prepared by the Global Harmonization Task Force with modification to the Note in the definition.

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 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.