MEDITSIINISEADMETE STERILISEERIMINE. NÕUDED MEDITSIINISEADMETELE, MIS PEAVAD KANDMA MÄRGISTUST "STERIILNE". OSA 1: NÕUDED LÕPLIKULT STERILISEERITUD MEDITSIINISEADMETELE

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

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 556-1:2024 sisaldab Euroopa standardi EN 556-1:2024 ingliskeelset teksti.	This Estonian standard EVS-EN 556-1:2024 consists of the English text of the European standard EN 556-1:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.07.2024.	Date of Availability of the European standard is 03.07.2024.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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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 European Standard was approved by CEN on 19 May 2024.

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

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

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Contents

Page

European foreword ... **3**

Introduction ... **4**

1 Scope ... **5**

2 Normative references ... **5**

3 Terms and definitions ... **5**

4 Requirements ... **7**

Annex ZA (informative) **Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** ... **8**

Annex ZB (informative) **Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered** ... **11**

Bibliography ... **13**

European foreword

This document (EN 556-1:2024) has been prepared by 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 January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

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 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*.

EN 556-1:2024 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.

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

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Türkiye and the United Kingdom.

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 management 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 are 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 EN 566 specifies the requirements for an aseptically processed medical device to be designated "STERILE".

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;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body;

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