SVENSK STANDARD
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Sterilisering av medicintekniska produkter – Krav för märkning med symbolen ”STERILE” –
Del 2: Krav på aseptiskt tillverkade medicintekniska produkter

Sterilization of medical devices – Requirements for medical devices to be designated ”STERILE” –
Part 2: Requirements for aseptically processed medical devices

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Europastandarden EN 556-2:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 556-2:2015.

Denna standard ersätter SS-EN 556-2:2004, utgåva 1.

The European Standard EN 556-2:2015 has the status of a Swedish Standard. This document contains the official English version of EN 556-2:2015.

This standard supersedes the Swedish Standard SS-EN 556-2:2004, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 556-2

September 2015

ICS 11.080.01

Supersedes EN 556-2:2003

English Version

Sterilization of medical devices - Requirements for medical devices to be designated ''STERILE" - Part 2: Requirements for aseptically processed medical devices

Stérilisation des dispositifs médicaux - Exigences relatives aux dispositifs médicaux en vue d'obtenir l'étiquetage " STÉRILE " - Partie 2 : Exigences pour les dispositifs médicaux soumis à un traitement aseptique

Sterilisation von Medizinprodukten - Anforderungen an Medizinprodukte, die als ''STERIL'' gekennzeichnet werden - Teil 2: Anforderungen an aseptisch hergestellte Medizinprodukte

This European Standard was approved by CEN on 24 July 2015.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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European foreword

This document (EN 556-2:2015) 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 March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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

This document supersedes EN 556-2:2003.

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 relationship with EU Directive(s), see informative Annexes ZA, ZB and ZC, which are integral parts 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*;

— *Part 2: Requirements for aseptically processed medical devices* [this document].

The following amendments have been made in updating the document from EN 556-2:2003:

a) normative references have been updated;

b) terms and definitions have been aligned with ISO/TS 11139 and EN ISO 13408-1;

c) requirements on validation and routine control have been revised;

d) Table 1 and Table 2 on acceptance limits and actions for occurrence of non-sterile units in process simulations in initial performance qualification and in periodic requalification, respectively, have been added;

e) editorial revision according to the CEN Internal Regulations.

Annexes designated ‘informative’ are given only for information. In this standard Annexes ZA, ZB and ZC are informative.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Medical devices designated 'STERILE' are prepared using appropriate and validated methods. Whenever possible, sterile medical devices are terminally-sterilized using a properly validated and controlled sterilization process (see EN 556-1, EN ISO 11135, EN ISO 11137-1, EN ISO 14160, EN ISO 14937, EN ISO 17665-1, EN ISO 20857 and EN ISO 25424). When a medical device is intended to be sterile but cannot be terminally-sterilized, aseptic processing is the method of manufacture (see EN ISO 13408-1).

Aseptic processing necessitates that either:

a) the entire product is sterilized and then introduced into a sterilized package; or

b) components of the product are sterilized, then further processed/assembled, and the final product packed into a sterilized package.

Processing/assembly and packaging are carried out in a manner that minimizes the opportunity for items to become re-contaminated by carrying out these operations in a controlled environment in which microbial and particulate levels are maintained at or below defined limits and human intervention is minimized.

NOTE EN ISO 15223-1 specifies the label applied to aseptically processed medical devices as STERILE A.

1 Scope

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), designating that a medical device is 'STERILE' is permissible when a validated manufacturing and sterilization process has been applied. Requirements for validation and routine control of aseptic processes are specified in EN ISO 13408-1. Specific requirements for the aseptic processing of solid medical devices and combination products are specified in ISO 13408-7.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)*

EN ISO 11137-1:2015, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)*

EN ISO 13408-2:2011, *Aseptic processing of health care products — Part 2: Filtration (ISO 13408-2:2003)*

EN ISO 13408-5:2011, *Aseptic processing of health care products — Part 5: Sterilization in place (ISO 13408-5:2006)*

EN ISO 13485:2012, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)*

EN ISO 14160:2011, *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 14160:2011)*

EN ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)*

EN ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

EN ISO 20857:2013, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)*

EN ISO 25424:2011, *Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2009)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
aseptic processing
handling of sterile product, containers and/or devices in a controlled environment, in which the air supply, materials, equipment and personnel are regulated to maintain sterility

[SOURCE: EN ISO 13408-1:2015, 3.4]

3.2
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO/TS 11139:2006, 2.2]

3.3
medical device
instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, 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 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 for medical purposes by means of *in vitro* examination of specimens derived from the human body

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[SOURCE: EN ISO 13485:2012, 3.7]

3.4
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

[SOURCE: ISO/TS 11139:2006, 2.30]

3.5
process simulation
exercise that simulates the manufacturing process or portions of the process in order to demonstrate the capability of the aseptic process to prevent biological contamination

[SOURCE: ISO 13408-7:2012, 3.2]

Note 1 to entry: Other terms for process simulation include media fill, simulated process fill, simulated filling operation, broth trial, broth fill.

3.6
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process

[SOURCE: ISO/TS 11139:2006, 2.40]

3.7
sterility
state of being free from viable micro-organisms

[SOURCE: ISO/TS 11139:2006, 2.45]

3.8
sterile
free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, 2.43]

3.9
terminally-sterilized
condition of a medical device which has been exposed to a sterilization process in a packaged or assembled form that maintains the sterility of the medical device or a defined portion thereof

[SOURCE: EN 556-1:2001, 3.5]

3.10
test for sterility
technical operation defined in an official Pharmacopoeia performed on product following exposure to a sterilization process

[SOURCE: ISO/TS 11139:2006, 2.53]

Note 1 to entry: For the purpose of this document, the official Pharmacopoeia that applies is the European Pharmacopoeia.

3.11
validation
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[SOURCE: ISO/TS 11139:2006, 2.55]