SLOVENSKI STANDARD

SIST EN 556-2:2004

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Sterilizacija medicinskih pripomoļ kov ï Zahteve za medicinske pripomoļ ke, ki morajo biti oznaļ eni s "STERILNO" ï 2. del: Zahteve za medicinske pripomoļ ke, izdelane v aseptiļ nem okolju

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

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

Stérilisation des dispositifs médicaux - Exigences relatives aux dispositifs médicaux en vue d'obtenir l'étiquetage "STERILE" - Partie 2: Exigences pour les dispositifs médicaux préparés aseptiquement

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ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

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EUROPEAN STANDARD

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

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This European Standard was approved by CEN on 1 October 2003.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

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Contents

Foreword

This document (EN 556-2:2003) 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 June 2004, and conflicting national standards shall be withdrawn at the latest by June 2004.

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 Annex ZA, which is an integral part of this standard.

This standard has been considered by CEN/TC 204 as one of a sequence of European Standards concerned with sterilization processes and their control. The other standards in this series are:

EN 550	Sterilization of medical devices -Validation and routine control of ethylene oxide sterilization.
EN 552	Sterilization of medical devices -Validation and routine control of sterilization by irradiation
EN 554	Sterilization of medical devices -Validation and routine control of moist heat sterilization
EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally-sterilized medical devices
EN 1174	Sterilization of medical devices - Estimation of the population of micro-organisms on product
EN ISO 14160	Sterilization of single uses medical devices incorporating materials of animal origin - Validation and routine control of the sterilization by liquid chemical sterilants (ISO 14160:1998)
EN ISO 14937	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 14937:2000)
prEN 13824	Sterilization of medical devices - Validation and routine control of aseptic processes - Requirements and guidance (in preparation)

Annexes designated ‘informative’ are given only for information. In this standard annex ZA is 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland 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 550, EN 552, EN 554 and EN ISO 14937). When a medical device is intended to be sterile but cannot be terminally-sterilized, aseptic processing is the method of manufacture (see prEN 13824 and EN ISO 14160).

Aseptic processing requires that either

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

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

Processing and packaging are carried out in a manner that minimizes the opportunity for items to become recontaminated and in a controlled environment in which microbial and particulate levels are maintained at or below defined limits and human intervention is minimized.

NOTE: EN 980 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 only permissible when a validated sterilization process has been applied. Requirements for validation and routine control of aseptic processes are specified in prEN 13824 (in preparation).

2 Normative references

This Europeans Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 550, *Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization*

EN 552, *Sterilization of medical devices - Validation and routine control of sterilization by irradiation*

EN 554, *Sterilization of medical devices - Validation and routine control of sterilization by moist heat*

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

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply

3.1
aseptic processing
handling and filling of sterile containers and devices, or their components, in a controlled environment in which the air supply, materials, equipment and personnel are regulated to control microbial and particulate contamination to acceptable levels.

NOTE Aseptic processing can include formulation (compounding), filtration and filling into pre-sterilized containers.

3.2
bioburden
population of viable micro-organisms on a product and/or package

3.3
media fills
simulation of an aseptic process in which a microbial growth medium is used to assess the effectiveness of the controls applied

NOTE Media fills are synonymous with process simulation tests, simulated process fills, simulated filling operations, broth trials, broth fills.

3.4
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal 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.

3.5
sterility
state of being free from viable micro-organisms

3.6
sterile
condition of a medical device that is free from viable micro-organisms

3.7
terminally-sterilized
condition of a medical device that 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

3.8
test for sterility
technical operation defined in an official Pharmacopoeia generally applied to sterilized or aseptically processed product

NOTE For the purpose of this European Standard, the official Pharmacopoeia that applies is the European Pharmacopoeia.

4 Requirements

4.1 General Requirements

For an aseptically processed medical device, the following requirements pertaining to the aseptic process shall apply:

a) the manufacturing environment in which the aseptic process is conducted is specified, and records demonstrating compliance with the specification throughout the conduct of the process are prepared and maintained;

b) the processes employed to sterilize product, components, equipment and packaging are validated and routinely controlled in compliance with EN 550, EN 552, EN 554, EN ISO 14937 or EN ISO 14160, as applicable;

c) requirements for the competence of personnel and methods for their training are specified, and records demonstrating that the specified competence has been achieved are prepared and maintained;

d) interventions occurring within the aseptic process, which are permitted, are identified, documented and validated;

e) records of all interventions occurring within the aseptic process are prepared and maintained;

f) acceptance criteria for tests for sterility carried out on product after aseptic processing are specified and records of tests for sterility performed against these criteria are prepared and maintained;

g) the frequency for the conduct of media fills is specified and

h) when media fills are undertaken, the observed frequency of occurrence of a non-sterile unit of microbial growth medium is less than 1×10^{-3} .

NOTE 1 prEN 13824 specifies detailed requirements for and guidance on the quality of the manufacturing environment, the training of personnel, the management of interventions, the performance of tests for sterility and the performance of media fills.

NOTE 2 EN 980 specifies a graphical symbol STERILE A for the labelling of aseptically processed medical devices.

4.2 Compliance, validation and routine control

Compliance shall be shown by the manufacturer or supplier through provision of documentation and records of the validation and routine control of the aseptic process.

NOTE Evidence that an aseptically processed medical device is sterile comes from:

i) the validation of the aseptic process and subsequent revalidations that demonstrate the initial and continued acceptability of the process, and

ii) review of completeness and accuracy of information, gathered during routine monitoring and subsequent actions, which demonstrates that the validated process has been delivered.

4.3 Documentation and records

The documentation and records shall be retained as specified in EN ISO 13485.