SLOVENSKI STANDARD
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Sterilizacija medicinskih pripomočkov - Zahteve za medicinske pripomočke, ki morajo biti označeni s "STERILNO" - 2. del: Zahteve za medicinske pripomočke, izdelane v aseptičnem 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 STÉRILE - Partie 2: Exigences pour les dispositifs médicaux soumis à un traitement aseptique

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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.

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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.

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

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Foreword

This document (prEN 556-2:2014) 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 556-2:2003.

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 Directives.

For relationship with EU Directives, see informative Annex ZA, ZB and ZC, which are integral parts of this document.

The other standards in this series are:

EN 556-1 Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally-sterilized medical devices

EN ISO 11135-1 Sterilization of health care products - Requirements for the development, validation and routine control of a sterilization process for medical devices - Ethylene oxide

EN ISO/TS 11135-2 Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO 11135-1

EN ISO 11137-1 Sterilization of health care products - Radiation – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

EN ISO 11137-2 Sterilization of health care products - Radiation – Part 2: Establishing the sterilization dose

EN ISO 11137-3 Sterilization of health care products Radiation – Part 3: Guidance on dosimetric aspects

EN ISO 11737-1 Sterilization of medical devices - Microbiological methods - Part 1: Determination of the population of microorganisms on products

EN ISO 11737-2 Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process

EN ISO 13408-1, Aseptic processing of health care products - Part 1: General requirements

EN ISO 13408-3 Aseptic processing of health care products - Part 3: Lyophilization

EN ISO 13408-4 Aseptic processing of health care products - Part 4: Clean-in-place technologies

EN ISO 13408-5 Aseptic processing of health care products - Part 5: Sterilization-in-place

EN ISO 13408-6 Aseptic processing of health care products - Part 6: Isolator systems

EN ISO 13408-7 Aseptic processing of health care products – Part 7: Alternative processes for medical devices and combination products [Under ballot for adoption as EN]

EN ISO 14160 Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of the sterilization by liquid chemical sterilants

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

EN ISO 17664 Sterilization of medical devices - Information to be provided by the supplier for the reprocessing of resterilizable devices

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

CEN/ISO TS 17665-2 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

EN ISO 20857 Sterilization of health care products – Dry heat – Requirements for the development, validation and routine control of an industrial sterilization process for medical devices

EN ISO 25424 Sterilization of medical devices – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of sterilization process for medical devices

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

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 11135-1, EN ISO 11137-1, EN ISO 14160, EN ISO 14937, EN ISO 17665-1, EN ISO 20857, or 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 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/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 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 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 EN ISO 13408-7 (in preparation).

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 11135-1, *Sterilization of health care products - Requirements for the development, validation and routine control of a sterilization process for medical devices - Ethylene oxide (ISO 11135-1)*

EN ISO 11137-1 + A1, *Sterilization of health care products Radiation – Part 1- Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11137-1)*

EN ISO 13408-5, *Aseptic processing of health care products - Part 5: Sterilization-in-place*

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

EN ISO 14160, *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)*

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)*

EN ISO 17665-1, *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)*

EN ISO 20857, *Sterilization of health care products – Dry heat – Requirements for the development, validation and routine control of an industrial sterilization process for medical devices (ISO 20857)*

EN ISO 25424, *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)*

3 Terms and definitions

For the purposes of this European Standard, 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 13408-1:2008]

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

[SOURCE: ISO 11139:2005]

3.3
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.

[SOURCE: EN ISO 13485:2003]

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 11139:2005]

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

[SOURCE: EN ISO 13408-7 – in preparation]

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 11139:2005]

3.7
sterility
state of being free from viable micro-organisms

[SOURCE: ISO 11139:2005]

3.8
sterile
free from viable microorganisms

[SOURCE: ISO 11139:2005]

3.9
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

[SOURCE: ISO 11139:2005]

3.10
test for sterility
technical operation defined in an official Pharmacopoeia generally applied to sterilized or aseptically processed product

[SOURCE: ISO 11139:2005]

Note 1 to entry: For the purpose of this European Standard, 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 11139:2005]

4 Requirements

4.1 Validation and routine control

For an aseptically processed medical device, the following 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 ISO 11135-1, EN ISO 11137-1, EN ISO 14160, EN ISO 13408-2, EN ISO 13408-5, EN ISO 14937, EN ISO 17665-1, EN ISO 20857, or EN ISO 25424 as applicable;

   NOTE 1. Usually, such sterilization processes are validated and routinely controlled to achieve a probability of a viable microorganism surviving on a sterilized item of 10^{-6} or less.

c) the 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;