SLOVENSKI STANDARD
SIST EN 556:2000

01-januar-2000

Sterilizacija medicinskih pripomoļ kov - Zahteve za konļ no sterilizirane medicinske pripomoļ ke, ki morajo biti oznaļ eni kot "sterilni"

Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "Sterile"

Sterilisation von Medizinprodukten - Anforderungen für in der Endverpackung zu sterilisierende Medizinprodukte, die als "Steril" gekennzeichnet werden

Stérilisation des dispositifs médicaux - Exigences pour les dispositifs médicaux ayant subi une stérilisation terminale étiquetés "Stérile"

Ta slovenski standard je istoveten z: **EN 556:1994 + A1:1998**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

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EUROPEAN STANDARD
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English version

Sterilization of medical devices - Requirements for terminally - sterilized medical devices to be labelled "Sterile"

Stérilisation des dispositifs médicaux - Exigences pour les dispositifs médicaux ayant subi une stérilisation terminale étiquetés "Stérile"

Sterilisation von Medizinprodukten - Anforderungen für in der Endverpackung zu sterelisierende Medizinprodukte, die als "Steril" gekennzeichnet werden

This amendment A1 modifies the European Standard EN 556:1994; it was approved by CEN on 1 June 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This amendment 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 Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This Amendment EN 556:1994+A1:1998 to EN 556:1994 has been prepared by Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

This Amendment to the European Standard EN 556:1994 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 1999, and conflicting national standards shall be withdrawn at the latest by February 1999.

This Amendment to the European Standard EN 556:1994 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).

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

A *sterile* product item is one which is free of viable micro-organisms. The 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 the requirements for quality systems for medical devices (see EN 46001 or EN 46002) may, prior to sterilization, have micro-organisms on them, albeit is 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 micro-organisms by physical and/or chemical agents used to sterilize *medical devices* often approximates to an exponential relationship; inevitably this means that there is always a finite probability that a micro-organism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of micro-organisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one item in a population of items subjected to sterilization processing cannot be guaranteed and the sterility of the processed population of items has to be defined in terms of the probability of the existence of a non-sterile item in that population.

The European Pharmacopoeia Commission considers that a product may be regarded as *sterile* when the theoretical level of not more than one living micro-organism is present in 1×10^6 sterilized units of the final product. The principles of the standards EN 550, EN 552 and EN 554 are applicable irrespective of the stated probability.

Requirements for the quality system for the design/development, production, installation and servicing of *medical devices* are given in EN 46001 and EN 46002 which supplement the EN 29000 series of European Standards.

The EN 29000 series of standards designates certain processes used in manufacture as "special" if the results cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because process efficacy cannot be verified by inspection and testing of the product. For this reason, 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 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

1.1 This European Standard specifies the requirements for a terminally-sterilized medical device to be labelled "STERILE".

NOTE: For the purpose of the EC Directives for medical devices and for active implantable medical devices (see annex A), labelling a medical device "STERILE" is only permissible when a validated sterilization process has been used. Requirements for the validation and routine control of processes for the sterilization of medical devices are specified in EN 550, EN 552 and EN 554.

1.2 This European Standard is not applicable to *in vitro* diagnostic medical devices.

2 Normative references

This European 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.

EN 46001 : 1993	Quality systems - Medical devices - Particular requirements for the application of EN 29001
EN 46002 : 1993	Quality systems - Medical devices - Particular requirements for the application of EN 29002

3 Definitions

For the purposes of this standard, the following definitions apply.

3.1 **bioburden:** Population of viable micro-organisms on a product and/or a package.

3.2 **medical device:** (The definition given in EN 46001 applies.)

3.3 **sterility:** State of being free from viable micro-organisms.

3.4 sterile: Condition of a medical device that is free from viable micro-organisms.

NOTE: Because of the nature of microbial inactivation kinetics, it is not possible to verify if any one device, selected at random from a sterilized population of devices, conforms to the condition defined in **3.3**. It is not practicable, therefore, to apply this definition to the condition of all devices comprising a sterilized population.

4 Requirements

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

NOTE: In certain instances, the use of a probability greater than that specified in this standard may be acceptable to regulatory authorities. Such instances require individual consideration of the compatibility of the medical device with recognized sterilization methods and of evidence of benefit for patient care. It is not possible to encompass these instances within a standard, but mechanisms exist within a regulatory system to permit their acceptance.

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 achieving the requirement (**4.1**).

The documentation and records shall be retained as specified in **4.5.1** and **4.16** of EN 46001: 1993 or **4.4.1** and **4.15** of EN 46002: 1993.

NOTE 1: The achievement of sterility is predicted from the *bioburden* level on products, the resistance of the micro-organisms comprising that *bioburden* and the extent of treatment imposed during sterilization.

NOTE 2: It is necessary to maintain sterility during handling, storage and delivery until use of the sterile device.