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ICS 11.080.01

STERILISATION OF MEDICAL DEVICES - REQUIREMENTS FOR MEDICAL DEVICES TO BE DESIGNATED "STERILE" - PART 1: REQUIREMENTS FOR TERMINALLY STERILISED MEDICAL DEVICES

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English version
Version Française
Deutsche Fassung

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 STERILE - Partie 1: Exigences relatives aux dispositifs médicaux stérilisés au stade terminal

Sterilisation von Medizinprodukten - Anforderungen an Medizinprodukte, die als 'STERIL' gekennzeichnet werden - Teil 1: Anforderungen an Medizinprodukte, die in der Endpackung sterilisiert wurden

This corrigendum becomes effective on 20 September 2006 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 20 septembre 2006 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 20.September 2006 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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English version

Note to 4.1

Delete the second sentence (beginning 'Such permission requires…') and replace it by “Such permission depends on the individual situation, including consideration of the risk management activities (see, for example, EN ISO 14971) undertaken by the manufacturer of the medical device.“

Bibliography

Delete reference 7 to EN 1441 and replace it with EN ISO 14971:2000 *Medical devices - Application of risk management to medical devices (ISO 14971:2000)*

Deutsche Fassung

Anmerkung zu 4.1

Der zweite Satz (beginnend mit "Eine derartige Genehmigung …") ist zu streichen und durch den folgenden Satz zu ersetzen: "Eine derartige Genehmigung hängt von der individuellen Situation ab, einschließlich der Berücksichtigung der vom Hersteller des Medizinproduktes durchgeführten Aktivitäten zum Risikomanagement (siehe z. B. EN ISO 14971)."

Literaturhinweise

Der Literaturhinweis 7 auf EN 1441 ist zu streichen und durch eine Referenz auf EN ISO 14971:2000, *Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2000)* zu ersetzen.

EUROPEAN STANDARD
NORME EUROPÉENNE
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This European Standard was approved by CEN on 18 August 2001.

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

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Management Centre: rue de Stassart, 36 B-1050 Brussels

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Contents

Foreword

This European Standard 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 April 2002, and conflicting national standards shall be withdrawn at the latest by April 2002.

This European Standard supersedes EN 556:1994.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC 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*
prEN 556-2	*Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 2: Requirements for aseptically processed medical devices (in preparation)*
EN 1174	*Sterilization of medical devices - Estimation of the population of micro-organisms on product*
EN ISO 14160	*Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of 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)*

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, 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. 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 systems for medical devices (see EN ISO 13485:2000 or EN ISO 13488:2000) may, prior to sterilization, have micro-organisms 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 micro-organisms 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 micro-organism will survive. 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 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 micro-organism 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 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 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 European Standard specifies the requirements for a terminally-sterilized *medical device* to be designated *'STERILE'*. Part 2 of 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), designation of a medical device as *'STERILE'* is only permissible when a validated sterilization process has been applied. Requirements for validation and routine control of processes for the sterilization of *medical devices* are specified in EN 550, EN 552, EN 554, EN ISO 14160 and EN ISO 14937.

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 (including amendments).

EN ISO 13485:2000, *Quality systems - Medical devices - Particular requirements for the application of EN/ISO 9001 (revision of EN 46001:1996) (identical to ISO 13485:1996)*

EN ISO 13488:2000, *Quality systems - Medical devices - Particular requirements for the application of EN/ISO 9002 (revision of EN 46002:1996) (identical to ISO 13488:1996)*

3 Terms and definitions

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

NOTE Terms defined in this clause are set in Italic type throughout the text of this standard.

3.1

bioburden

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

3.2

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 purpose 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.

3.3

sterility

state of being free from viable micro-organisms

3.4

sterile

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

3.5

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

4 Requirements

4.1 For a terminally-sterilized *medical device* to be designated *"STERILE"*, the theoretical probability of there being a viable micro-organism present on/in the device shall be equal to or less than $1x10^{-6}$.

NOTE Permission for acceptance of a probability greater than that specified in **4.1** may be sought through the appropriate regulatory bodies. Such permission requires consideration of the individual situation, including consideration of the risk analysis (see, for example, EN 1441) undertaken by the manufacturer of the *medical device.*

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 fulfilling **4.1**.

The documentation and records shall be retained as specified in EN ISO 13485:2000, **4.5** and **4.16** or EN ISO 13488:2000, **4.5** and **4.16**.

NOTE 1 Evidence that a *medical device* is *sterile* comes from: i) the initial validation of the sterilization process and subsequent revalidations that demonstrate the acceptability of the process; and ii) information gathered during routine control and monitoring which demonstrates that the validated process has been delivered in practice.

NOTE 2 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.