SLOVENSKI STANDARD

SIST EN ISO 14937:2001

01-november-2001

Sterilizacija izdelkov za zdravstveno nego - Splošne zahteve za opredelitev lastnosti sterilizacijskih sredstev in za razvoj, validacijo ter rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO 14937:2000)

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)

Sterilisation von Produkten für die Gesundheitsfürsorge - Allgemeine Anforderungen an die Charakterisierung eines Sterilisiermittels und an die Entwicklung, Validierung und Routineüberwachung eines Sterilisationsverfahrens für Medizinprodukte (ISO 14937:2000)

Stérilisation des produits de santé - Exigences générales pour la caractérisation d'un agent stérilisant et pour le développement, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux (ISO 14937:2000)

Ta slovenski standard je istoveten z: **EN ISO 14937:2000**

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English version

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)

Stérilisation des produits de santé - Exigences générales pour la caractérisation d'un agent stérilisant et pour le développement, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux (ISO 14937:2000)

Sterilisation von Medizinprodukten - Allgemeine Anforderungen an die Charakterisierung eines Sterilisiermittels und an die Entwicklung, Validierung und Routineüberwachung eines StSterilisationsverfahrens für Medizinprodukte (ISO 14937:2000)

This European Standard was approved by CEN on 15 December 2000.

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.

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

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Ref. No. EN ISO 14937:2000 E

Foreword

The text of the International Standard ISO 14937:2000 has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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 2001, and conflicting national standards shall be withdrawn at the latest by June 2001.

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 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.

Endorsement notice

The text of the International Standard ISO 14937:2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

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).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 10012-1	1992	Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment	EN 30012-1	1993
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997
ISO 11737-2	1998	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process	EN ISO 11737-2	2000
ISO 13485	1996	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001	EN ISO 13485	2000
ISO 13488	1996	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9002	EN ISO 13488	2000

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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

Stérilisation des produits de santé — Exigences générales pour la caractérisation d'un agent stérilisant et pour le développement, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14937 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

Annexes A, B, C and D form a normative part of this International Standard. Annexes E and ZA are for information only.

Introduction

A sterile medical device is one which is free of viable microorganisms. When it is necessary to supply a sterile medical device, International Standards specifying requirements for validation and routine control of sterilization processes require that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality systems (see, for example, ISO 13485 and ISO 13488) or which have been subjected to a cleaning process as part of their reprocessing in a health care establishment may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent. Inevitably this means that there is always a finite probability that a microorganism 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 microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be guaranteed, and the sterility of a processed population has to be defined in terms of the probability of there being a viable microorganism present on a product.

This International Standard describes requirements which will enable sterilizer manufacturers, medical device manufacturers and health care facilities to demonstrate that a process intended to sterilize medical devices has appropriate microbicidal activity, and that this activity is both reliable and reproducible, such that the relationship for the inactivation of microorganisms can be extrapolated with reasonable confidence to low levels of probability of there being a viable microorganism present on a product after sterilization processing. This International Standard does not specify the maximal value to be taken by this probability; specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556 and AAMI ST67).

Generic requirements of the quality system for design/development, production, installation and servicing are given in the ISO 9000 series and particular requirements for quality systems for medical device production in ISO 13485 and ISO 13488. The standards for quality systems recognize that, for certain processes used in manufacturing or reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this respect, suitable for its intended use. Attention is given to a number of factors, including:

a) for a manufacturing process, the microbiological status of incoming raw materials and/or components;

b) the validation and routine control of the cleaning and disinfection procedures used during reprocessing;

c) the control of the environment in which the product is manufactured, assembled and packaged, together with control of personnel and their hygiene; and,

d) the manner in which the items are packaged and the conditions under which the sterilized items are stored.

The type of contamination on a product to be sterilized varies, and this impacts upon the effectiveness of a sterilization process. Products that have been used in a health care setting, and are being presented for resterilization in accordance with the manufacturer's instructions, should be regarded as a special case. There is the potential for such products to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination, in spite of the application of a cleaning process. Hence, particular attention is given to the validation and control of the cleaning and disinfection processes used during reprocessing.

Sterilization technology is at several levels of development and application. There are processes which are developed and have been in use for appreciable periods, and there are processes which are being developed and introduced either for sterilization of specific products or for general application. Furthermore, there may be processes which have yet to be discovered. Experience has identified the requirements which are appropriate for existing sterilization technologies, and these requirements have been specified in International Standards specific to each established process. The intention in developing this International Standard is to use this experience to provide, for suppliers of sterilization technologies, to their users and to regulatory authorities, a knowledge of the relevant general requirements that will allow development of additional sterilization technologies to continue within a broad framework until sufficient experience, confidence and demand exist to justify the preparation of a specific International Standard.

This International Standard has three distinct applications:

— for manufacturers of health care products who wish to apply to their products a sterilization process for which a specific International Standard does not exist; and,

— for manufacturers and users of sterilization systems in health care settings for which a specific International Standard does not exist; and,

— to provide a framework for the preparation or revision of standards for specific sterilization processes.

The responsibility for carrying out the activities required by this International Standard will vary from case to case. This International Standard requires that the responsibilities of the various parties be defined (see 4.1.1) but does not specify to whom the responsibilities are allocated. Annex E provides guidance on allocation of responsibility.