Tervishoiutoodete steriliseerimine. Üldnõuded steriliseerimisaine iseloomustusele ja meditsiiniseadmete steriliseerimisprotsessi väljatöötamisele, valideerimisele ja tavakontrollile

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

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 14937:2001 sisaldab Euroopa standardi EN ISO 14937:2000 + AC:2003 + AC:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 18.05.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 14937:2001 consists of the English text of the European standard EN ISO 14937:2000 + AC:2003 + AC:2005. This document is endorsed on 18.05.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard specifies general requirements for the characterization of a sterilizing agent, and for the development, validation and routine of a sterilization process for medical devices.	**Scope:** This International Standard specifies general requirements for the characterization of a sterilizing agent, and for the development, validation and routine of a sterilization process for medical devices.

ICS 11.080.01

Võtmesõnad: birth control, characterisatio, health protection, medical products, sample surveys, specification, specification (approval), specifications, sterilization, sterilization (birth control), sterilization (hygiene), sterilizers, surveillance (approval), validation

EUROPEAN STANDARD
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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 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)

This European Standard was approved by CEN on 2000-12-15.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Ref. No. EN ISO 14937 : 2000 E

Foreword

International Standard

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,

which was prepared by ISO/TC 198 'Sterilization of health care products' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 204 'Sterilization of medical devices', the Secretariat of which is held by BSI, as a European Standard.

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 the relevant EU Directives.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by June 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the 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 publications are listed in Annex ZA (normative).

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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.

1 Scope

1.1 This International Standard specifies general requirements for the characterization of a sterilizing agent, and for the development, validation and routine control of a sterilization process for medical devices.

1.2 This International Standard applies to sterilization processes in which microorganisms are inactivated by physical and/or chemical means.

1.3 This International Standard does not apply to processes that rely solely on physical removal of microorganisms (for example, filtration).

1.4 This International Standard does not describe detailed test procedures for assessing microbial inactivation.

1.5 This International Standard is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized and the organization with responsibility for sterilizing the medical device.

1.6 This International Standard does not supersede or modify published International Standards for particular sterilization processes.

NOTE 1 Although the scope of this International Standard is limited to medical devices, the principles described may also be applied to other health care products.

NOTE 2 Sterilization processes validated and controlled in accordance with the requirements of this International Standard should not be assumed to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment.*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances using health-based risk assessment.*

ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General.*

ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements.*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Estimation of population of microorganisms on products.*

ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process.*

ISO 13485, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001.*

ISO 13488, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002.*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements.*

3 Terms and definitions

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

3.1
bioburden
population of viable microorganisms on a product and/or a package

3.2
biological indicator
microbiological test system providing a defined resistance to a specified sterilization process

3.3
change control
formal assessment and determination of the appropriateness of a proposed alteration to product or procedure

3.4
chemical indicator
system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process

3.5
development
act of elaborating a specification in preparation for validation

3.6
establish
determine by theoretical evaluation and confirm by experimentation

3.7
fault
one or more of the process parameters which lies outside of its/their specified tolerance(s)

3.8
health care product
medical device, medicinal product (pharmaceuticals and biologics) or *in vitro* diagnostic medical device