Meditsiiniseadmete steriliseerimine. Mikroobse populatsiooni hindamine tootel. Osa 1: Nõuded

Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11737-1:2006 sisaldab Euroopa standardi EN ISO 11737-1:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 29.05.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11737-1:2006 consists of the English text of the European standard EN ISO 11737-1:2006. This document is endorsed on 29.05.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: EN 1174. käesolev osa esitab üldised kriteeriumid, mida tuleb rakendada eluvõimeliste mikroorganismide populatsiooni hindamisel meditsiiniseadmetel, nende koostisosadel, toorainetel ja pakenditel. Mikroobse populatsiooni hindamine sisaldab nii mikroorganismide loendamist kui nende iseloomustamist.	**Scope:** This part of ISO 11737 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.

ICS 07.100, 07.100.10, 11.080, 11.080.01

Võtmesõnad: analüüs, hindamine, kontrollimine, kvaliteet, meditsiiniaparatuur, mikrobioloogiline, mikroorganismid, saastumine, steriliseerimine, tähistus

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11737-1

April 2006

ICS 07.100.10; 11.080.01

Supersedes EN 1174-1:1996, EN 1174-2:1996, EN 1174-3:1996

English Version

Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)

Stérilisation des dispositifs médicaux - Méthodes microbiologiques - Partie 1: Détermination d'une population de micro-organismes sur des produits (ISO 11737-1:2006)

Sterilisation von Medizinprodukten - Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (ISO 11737-1:2006)

This European Standard was approved by CEN on 23 March 2006.

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

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, 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 11737-1:2006: E

Foreword

This document (EN ISO 11737-1:2006) 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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document supersedes EN 1174-1:1996, EN 1174-2:1996 and EN 1174-3:1996.

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 Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 11737-1:2006 has been approved by CEN as EN ISO 11737-1:2006 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EC concerning *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EC concerning *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Communities under thos Directives and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of those Directives and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directives 90/385 EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EC concerning in vitro diagnostic medical devices

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Essential Requirements (ERs) of Directive 93/42/EEC	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10, 11, 12	7	8.3	2.3	In part
4, 5, 6, 7, 8, 9, 10, 11, 12		8.4	2.4	In part

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 11737-1

Second edition
2006-04-01

Sterilization of medical devices — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

Stérilisation des dispositifs médicaux — Méthodes microbiologiques —

Partie 1: Détermination d'une population de micro-organismes sur des produits

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11737-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11737-1:1995) which has been technically revised and ISO 11737-3:2004 whose contents it now incorporates.

ISO 11737 consists of the following parts, under the general title *Sterilization of medical devices — Microbiological methods*:

— *Part 1: Determination of a population of microorganisms on products*

— *Part 2: Tests of sterility performed in the validation of a sterilization process*

Introduction

A sterile medical device is one that is free of viable microorganisms. International standards that specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, 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 management systems (see, for example, ISO 13485) 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 is defined in terms of the probability of there being a viable microorganism present on a product item.

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognize that, for certain processes used in manufacturing, 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 is monitored routinely and the equipment is maintained.

International Standards specifying procedures for the validation and routine control of the processes used for the sterilization of medical devices have been prepared (see, for example, ISO 11135, ISO 11137 series and ISO 17665). However, 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. Furthermore, for the effective validation and routine control of a sterilization process, it is important to be aware of the microbiological challenge that is presented in the process, in terms of number, characteristics and properties of microorganisms.

The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. A knowledge of bioburden can be used in a number of situations as part of:

— validation and revalidation of sterilization processes;

— routine monitoring for control of manufacturing processes;

— monitoring of raw materials, components or packaging;

— assessment of the efficiency of cleaning processes;

— an overall environmental monitoring programme.

Bioburden is the sum of the microbial contributions from a number of sources, including raw materials, manufacturing of components, assembly processes, manufacturing environment, assembly/manufacturing aids (e.g., compressed gases, water, lubricants), cleaning processes and packaging of finished product. To control bioburden, attention must be given to the microbiological status of these sources.

It is not possible to enumerate the bioburden exactly and, in practice, a determination of bioburden is made using a defined method. Definition of a single method for use in the determination of bioburden in all situations is not practicable because of the wide variety of designs and materials of construction of medical devices. Nor is it possible to define a single technique to be used in all situations for the removal of microorganisms in preparation for enumeration. Furthermore, the selection of conditions for enumeration of microorganisms will be influenced by the types of microorganism likely to be present on or in medical devices.

This part of ISO 11737 specifies the requirements to be met in the determination of bioburden. The requirements are the normative parts of this part of ISO 11737 with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being a suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of this part of ISO 11737.

Sterilization of medical devices — Microbiological methods —

Part 1: Determination of a population of microorganisms on products

1 Scope

This part of ISO 11737 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.

NOTE 1 The nature and extent of microbial characterization is dependent on the intended use of the bioburden data.

This part of ISO 11737 does not specify requirements for the enumeration or identification of viral or protozoan contaminants.

NOTE 2 Furthermore, the requirements specified in this part of ISO 11737 are not intended to address the removal and detection of the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

This part of ISO 11737 does not specify requirements for the microbiological monitoring of the environment in which medical devices are manufactured.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*