Meditsiiniseadmete bioloogiline hindamine. Osa 7: Jäägid etüleenoksiidiga steriliseerimisest

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10993-7:2008 sisaldab Euroopa standardi EN ISO 10993-7:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10993-7:2008 consists of the English text of the European standard EN ISO 10993-7:2008.
Standard on kinnitatud Eesti Standardikeskuse 15.12.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 15.12.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.10.2008.	Date of Availability of the European standard text 15.10.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.100.20

Võtmesõnad: bioloogiline proov, bioloogilised testid, etüleenoksiid, keemilised jäägid, kindlaksmääramine, meditsiiniaparatuur, steriliseerimine, testimine

EUROPEAN STANDARD

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EN ISO 10993-7

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English Version

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène (ISO 10993-7:2008)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid- Sterilisationsrückstände (ISO 10993-7:2008)

This European Standard was approved by CEN on 23 September 2008.

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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 CEN Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 10993-7:2008: E

Foreword

This document (EN ISO 10993-7:2008) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological evaluation of medical devices” the secretariat of which is held by NEN.

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 2009, and conflicting national standards shall be withdrawn at the latest by October 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10993-7:1995.

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 EC Directives.

For relationship with EC Directives, see informative Annexes ZA and ZB, which are an integral part of this document.

NOTE : **The Essential Requirements of the Medical Devices Directives require that risks be reduced or eliminated as far as possible and, specifically, that risks posed by residues be minimized and risks posed by substances leaking from a device be reduced to a minimum. It is inherent in these Essential Requirements that, within the maximum limits specified by this standard, exposure to a genotoxic carcinogen should be reduced to levels as low as reasonably practicable, taking account of the generally acknowledged state of the art, the technological level existing at the time of design and technical and economic considerations compatible with a high level of health and safety.**

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, 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 the United Kingdom.

Endorsement notice

The text of ISO 10993-7:2008 has been approved by CEN as a EN ISO 10993-7:2008 without any modification.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

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

Table ZA — Correspondence between this International Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Note
4, 5	Annex I, 7.2 and 7.5	For presumption of conformity, the standard needs to be interpreted as explained in the European Foreword.

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

Annex ZB
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

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

Table ZB — Correspondence between this International Standard and Directive 90/385/EEC on active implantable medical devices

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Note
4, 5	Annex I, 9	For presumption of conformity, the standard needs to be interpreted as explained in the European Foreword.

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

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Introduction

Requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices are given in International Standards developed by ISO/TC 198. Certain requirements relating to medical devices for biological testing, selection of tests, and the allocation of devices to categories are dealt with in a variety of International Standards developed by ISO/TC 194. The specific requirement for ethylene oxide and other sterilization process residuals was referred to ISO/TC 194. Other International Standards delineate particular requirements for biological testing for specific products.

As noted in the introduction to ISO 11135-1:2007, when determining the suitability of ethylene oxide (EO) for sterilization of medical devices, it is important to ensure that the levels of residual EO, ethylene chlorohydrin (ECH) and ethylene glycol (EG) pose a minimal risk to the patient in normal product use. Therefore, it is important that the use of alternative materials and sterilization processes be considered during product design and development. EO is known to exhibit a number of biological effects. In the development of this part of ISO 10993, consideration was given to these effects, which include irritation, organ damage, mutagenicity and carcinogenicity in humans and animals, and reproductive effects in animals. Similar consideration was given to the harmful effects of ECH and EG. In practice, for most devices, exposure to EO and ECH is considerably lower than the maximum values specified in this part of ISO 10993.

Moreover, when the choice for EO sterilization has been made, irrespective of the provisions of this part of ISO 10993, exposure to EO residues should be minimized. Requirements herein are in addition to the biological evaluation and testing requirements for each individually designed medical device as indicated in ISO 10993-1. The biological evaluation and testing requirements, combined with the EO-sterilization process residue limits, form the justification that an EO-sterilized device is acceptable for use. Maximum allowable residues for ethylene chlorohydrin (ECH), when ECH has been found to be present in medical devices sterilized with EO, are also specified. Local effects (e.g., irritation) have been considered and are incorporated in the tolerable contact limit (TCL) as given in 4.3.5.2 and Annex G for EO, and in 4.3.5.3 and Annex H for ECH.

Biological evaluation of medical devices —

Part 7:
Ethylene oxide sterilization residuals

1 Scope

This part of ISO 10993 specifies allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining compliance so that devices may be released. Additional background, including guidance and a flowchart showing how this document is applied, are also included in the informative annexes.

EO-sterilized devices that have no patient contact (e.g., *in vitro* diagnostic devices) are not covered by this part of ISO 10993.

NOTE This part of ISO 10993 does not specify limits for ethylene glycol (EG).

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 10993-1:—[1)], *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-17:2002, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 10993-17 and the following apply.

3.1
simulated-use extraction
extraction to demonstrate compliance with the requirements of this part of ISO 10993, by evaluating residue levels available to the patient or user from devices during the routine use of a device with water extraction to simulate product use

1) To be published. (Revision of ISO 10993-1:2003)