EESTI STANDARD EVS-EN ISO 10993-7:1999

Meditsiiniseadmete bioloogiline hindamine. Osa 7: Jäägid etüleenoksiidiga steriliseerimisest

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10993-7:1999 sisaldab Euroopa standardi EN ISO 10993-7:1995 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10993-7:1999 consists of the English text of the European standard EN ISO 10993-7:1995. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi käesolev osa määrab kindlaks lubatavad piirnormid etüleenoksiidi (EO) ja etüleenklorohüdriini (ECH) jääkidele etüleenoksiidiga steriliseeritud meditsiiniseadmetes.	**Scope:**

ICS 11.040.01, 11.080.01, 11.120.01

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

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ICS 11.060.10; 11.080; 11.120.20

Descriptors: Medical devices, ethylene oxide, sterilization, residues, biological evaluation.

English version

Biological evaluation of medical devices

Part 7: Ethylene oxide sterilization residuals
(ISO 10993-7:1995)

Evaluation biologique des dispositifs médicaux. Partie 7: Résidues de stérilisation à l'oxyde d'éthylène (ISO 10993-7:1995)

Biologische Beurteilung von Medizinprodukten. Teil 7: Ethylenoxid-Sterilisationsrückstände (ISO 10993-7:1995)

This European Standard was approved by CEN on 1995-06-23 and is identical to the ISO Standard as referred to.

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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 10993-7:1995 Biological evaluation of medical devices; ethylene oxide sterilization residuals,

which was prepared by ISO/TC 194 'Biological evaluation of medical devices' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 206 'Biocompatibility of medical and dental materials and devices' as a European Standard.

ISO 10993 comprises the following Parts:

Part 1 Guidance on selection of tests
Part 2 Animal welfare requirements
Part 3 Tests for genotoxicity, carcinogenicity and reproductive toxicity
Part 4 Selection of tests for interactions with blood
Part 5 Tests for cytotoxicity: *in vitro* methods
Part 6 Tests for local effects after implantation
Part 7 Ethylene oxide sterilization residuals
Part 9 Degradation of materials related to biological testing
Part 10 Tests for irritation and sensitization
Part 11 Tests for systemic toxicity
Part 12 Sample preparation and reference materials
Part 13 Identification and quantification of degradation products from polymers
Part 14 Identification and quantification of degradation products from ceramics
Part 15 Identification and quantification of degradation products from coated and uncoated metals and alloys
Part 16 General guidance on toxicokinetic study design for degradation products and leachables
Part 17 Glutaraldehyde and formaldehyde residues in industrially sterilized medical devices

Future Parts will deal with other relevant aspects of biological testing.

This European Standard has been prepared under a Mandate given to CEN by the Commission of the European Communities 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 April 1996 at the latest.

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

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of the International Standard ISO 10993-7:1995 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

Contents

Introduction

Requirements for the quality system for validation and routine monitoring of sterilization of medical products with gaseous ethylene oxide 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 under development by ISO/TC 194. The specific requirements 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.

When determining the suitability of ethylene oxide (EO) for sterilization of medical devices, it is important to ensure that the levels of residual EO and ethylene chlorohydrin (ECH) pose a minimal risk to the patient in normal product use. 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 ethylene glycol (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.

Product development and design should have considered the use of alternative materials and sterilization processes with the aim of minimizing exposure to residuals. Requirements herein are in addition to the biological testing requirements for each individually designed medical device as indicated in ISO 10993-1. The biological testing requirements, combined with the EO-sterilization process residue limits, form the justification that an EO-sterilized device is acceptable for use.

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 and guidance also is included in informative annexes.

EO-sterilized devices that have no patient contact (e.g. *in vitro* diagnostic devices) are not covered by this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 10993-3:1992, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.*

ISO 10993-10:1995, *Biological evaluation of medical devices — Part 10: Tests for irritation and sensitization.*

3 Definitions

For the purposes of this part of ISO 10993, the definitions given in ISO 10993-1 and the following definitions 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 using an extraction method using water that simulates product use.

NOTE 1 The burden of validation on the analytical laboratory is to demonstrate that the simulated-use extraction is carried out under conditions that provide the greatest challenge to the intended use. Product use simulation should be carried out assuming the device is assigned to the most stringent category probable for duration of exposure and should take into consideration both tissue(s) exposed and temperature of exposure.

3.2 exhaustive extraction: Extraction until the amount of EO or ECH in a subsequent extraction is less than 10 % of that detected in the first extraction, or until there is no analytically significant increase in the cumulative residue levels detected.

NOTE 2 As it is not possible to demonstrate the exhaustive nature of residual recovery, the definition of exhaustive extraction adopted is as above.

4 Requirements

NOTE 3 Information on the derivation of the limits in this part of ISO 10993 as well as other important background information and guidance relevant to the use of this part of ISO 10993 are contained in informative annexes.