SLOVENSKI STANDARD
SIST EN ISO 10993-7:2009/AC:2010

01-marec-2010

Biološko ovrednotenje medicinskih pripomočkov - 7. del: Ostanki po sterilizaciji z etilenoksidom - Popravek 1 (ISO 10993-7:2008/Cor 1:2009)

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Technical Corrigendum 1 (ISO 10993-7:2008/Cor 1:2009)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid-Sterilisationsrückstände (ISO 10993-7:2008/Cor 1:2009)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène - Rectificatif technique 1 (ISO 10993-7:2008/Cor 1:2009)

Ta slovenski standard je istoveten z: **EN ISO 10993-7:2008/AC:2009**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-7:2009/AC:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-7:2008/AC

November 2009
Novembre 2009
November 2009

ICS 11.100.20

English version
Version Française
Deutsche Fassung

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Technical Corrigendum 1 (ISO 10993-7:2008/Cor 1:2009)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène - Rectificatif technique 1 (ISO 10993-7:2008/Cor 1:2009)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid-Sterilisationsrückstände (ISO 10993-7:2008/Cor 1:2009)

This corrigendum becomes effective on 15 November 2009 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 15 novembre 2009 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 15.November 2009 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No.:EN ISO 10993-7:2008/AC:2009 D/E/F

Contents

Page

Foreword

This document (EN ISO 10993-7:2008/AC:2009) 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.

Endorsement notice

The text of ISO 10993-7:2008/Cor 1:2009 has been approved by CEN as a EN ISO 10993-7:2008/AC:2009 without any modification.

INTERNATIONAL STANDARD ISO 10993-7:2008
TECHNICAL CORRIGENDUM 1

Published 2009-11-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Biological evaluation of medical devices —

Part 7:
Ethylene oxide sterilization residuals

TECHNICAL CORRIGENDUM 1

Évaluation biologique des dispositifs médicaux —

Partie 7: Résidus de stérilisation à l'oxyde d'éthylène

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 10993-7:2008 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

Page iv, Foreword

Correct the title of Part 1 to read as follows:

— *Part 1: Evaluation and testing within a risk management process*

Page 10, 5.3 Procedure for product release using residue dissipation curves

Second paragraph, second sentence should read:

Dissipation of EO from most materials and devices follows first-order kinetics, i.e. (ln[EO]) ∝ (time after sterilization).

ICS 11.100.20 **Ref. No. ISO 10993-7:2008/Cor.1:2009(E)**

Published in Switzerland

Page 13

Equation (A.5) should read as follows:

$$\sigma^2 = \frac{\left(\sum y^2 - \frac{(\sum y)^2}{n}\right) - S \times \left(\sum xy - \frac{(\sum x \sum y)}{n}\right)}{n-2} \qquad \text{(A.5)}$$

Equation (A.6) should read as follows:

$$\lambda = \frac{\sum y}{n} \qquad \text{(A.6)}$$

Page 29, F.2.2 Intraocular lens limits

First paragraph, third sentence should read as follows:

This is necessary to prevent documented irritation responses of EO to ocular tissue (see References [44], [117], [118], [119] and [167]).

Second paragraph, third sentence should read as follows:

In such cases, References [44], [117], [118] and [119] indicate that the level of ECH that results in ocular toxicity is about four times greater than the corresponding EO level.

Page 30, F.2.5 Devices used in cardiopulmonary bypass procedures

First paragraph, delete the following sentences:

At this UTF, the allowable limit would increase to 21 mg EO. The EO limit reflects manufacturers' current ability to remove EO from these rather large devices.

Page 63, J.1.1

Footnote 9) should read as follows:

1 mmHg = 133,322 Pa or 760 mmHg = 101,325 kPa.