Polski Komitet Normalizacyjny

POPRAWKA do POLSKIEJ NORMY

ICS 11.100.20;

PN-EN ISO 10993-7:2009/AC

maj 2010

Wprowadza
EN ISO 10993-7:2008/AC:2009, IDT
ISO 10993-7:2008/AC1:2009, IDT

Dotyczy
PN-EN ISO 10993-7:2009

Biologiczna ocena wyrobów medycznych -- Część 7: Pozostałości po sterylizacji tlenkiem etylenu

Na wniosek Komitetu Technicznego nr 247
ds. Materiałów Medycznych i Biomateriałów
Poprawka do Normy Europejskiej EN ISO 10993-7:2008/AC:2009 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Technical Corrigendum 1 (ISO 10993-7:2008/Cor 1:2009)
ma status Poprawki do Polskiej Normy

nr ref. PN-EN ISO 10993-7:2009/AC:2010

EUROPEAN STANDARD

NORME EUROPÉENNE

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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

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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).

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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.