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Irish Standard
I.S. EN ISO 10993-7:2008

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

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I.S. EN ISO 10993-7:2008

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EUROPEAN STANDARD

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EN ISO 10993-7

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Supersedes EN ISO 10993-7:1995

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.

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

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

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Contents

Page

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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of an identical text or by endorsement, at the latest by April 2009, and conflicting national standards shall be withdrawn at the latest by October 2011.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.

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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.

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