SLOVENSKI STANDARD
SIST EN ISO 10993-7:2009/A1:2022

01-marec-2022

Biološko ovrednotenje medicinskih pripomočkov - 7. del: Ostanki po sterilizaciji z etilenoksidom - Dopolnilo A1: Uporaba dovoljenih mejnih vrednosti za novorojenčke in dojenčke (ISO 10993-7:2008/Amd 1:2019)

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid-Sterilisationsrückstände - Änderung 1 (ISO 10993-7:2008/Amd 1:2019)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène - Amendement 1 (ISO 10993-7:2008/Amd 1:2019)

Ta slovenski standard je istoveten z: **EN ISO 10993-7:2008/A1:2022**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-7:2009/A1:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-7:2008/A1

January 2022

ICS 11.100.20

English Version

Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)

Évaluation biologique des dispositifs médicaux - Partie 7: Résidus de stérilisation à l'oxyde d'éthylène - Amendement 1 (ISO 10993-7:2008/Amd 1:2019)

Biologische Beurteilung von Medizinprodukten - Teil 7: Ethylenoxid-Sterilisationsrückstände - Änderung 1 (ISO 10993-7:2008/Amd 1:2019)

This amendment A1 modifies the European Standard EN ISO 10993-7:2008; it was approved by CEN on 5 November 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO 10993-7:2008/A1:2022 E

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European foreword

This document (EN ISO 10993-7:2008/A1:2022) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological and clinical evaluation of medical devices” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 10993-7:2008 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2022, and conflicting national standards shall be withdrawn at the latest by July 2022.

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

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Endorsement notice

The text of ISO 10993-7:2008/Amd 1:2019 has been approved by CEN as EN ISO 10993-7:2008/A1:2022 without any modification.

INTERNATIONAL STANDARD

ISO 10993-7

Second edition
2008-10-15

AMENDMENT 1
2019-12

Biological evaluation of medical devices —

Part 7: Ethylene oxide sterilization residuals

AMENDMENT 1: Applicability of allowable limits for neonates and infants

Reference number
ISO 10993-7:2008/Amd.1:2019(E)

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Published in Switzerland

Foreword

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

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