

STN	Biologické hodnotenie zdravotníckych pomôcok Časť 7: Zvyšky po sterilizácii etylénoxidom Zmena A1: Použitelnosť dovolených medzí pre novorodencov a dojčatá (ISO 10993-7: 2008/Amd 1: 2019)	STN EN ISO 10993-7/A1 85 6516
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Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/22

Obsahuje: EN ISO 10993-7:2008/A1:2022, ISO 10993-7:2008/Amd 1:2019

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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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This amendment 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-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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of an identical text or by endorsement, at the latest by July 2022, and conflicting national standards shall be withdrawn at the latest by July 2022.

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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.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN