Nederlandse

norm

NEN-EN-ISO 10993-1 (en)

Biological evaluation of medical devices -
Part 1: Evaluation and testing
(ISO 10993-1:2003,IDT)

september 2003
ICS 11.100

Vervangt NEN-EN-ISO 10993-1:1998

Als Nederlandse norm is aanvaard:
- EN ISO 10993-1:2003,IDT
- ISO 10993-1:2003,IDT

Normcommissie 301 082 "Biocompatibiliteit en biologisch onderzoek"

NEN

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 10993-1

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Supersedes EN ISO 10993-1:1997

English version

Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)

Evaluation biologique des dispositifs médicaux - Partie 1: Evaluation et essais (ISO 10993-1:2003)

Biologische Beurteilung von Medizinprodukten Teil 1: Beurteilung und Prüfung (ISO 10993-1:2003)

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Ref. No. EN ISO 10993-1:2003 E

Foreword

This document (EN ISO 10993-1:2003) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 "Biocompatibility of medical and dental materials and 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of an identical text or by endorsement, at the latest by February 2004, and conflicting national standards shall be withdrawn at the latest by February 2004.

This document supersedes EN ISO 10993-1:1997.

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For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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NOTE FROM CMC The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZB for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of ISO 10993-1:2003 has been approved by CEN as EN ISO 10993-1:2003 without any modifications.

Annex ZA
(informative)

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Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

INTERNATIONAL STANDARD

ISO 10993-1

Third edition
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Biological evaluation of medical devices —

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Évaluation biologique des dispositifs médicaux —

Partie 1: Évaluation et essais

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