National Standards Authority of Ireland

STANDARD

I.S. EN ISO 10993-1:2003

ICS 11.100

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Tel: (01) 807 3838

BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 1: EVALUATION AND TESTING (ISO 10993-1:2003)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on: October 15, 2003

Price Code I

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-1

August 2003

ICS 11.100

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 Prüfungen (ISO 10993-1:2003)

This European Standard was approved by CEN on 28 July 2003.

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 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 Management Centre has the same status as the official versions.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

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

CORRECTED 2003-09-24

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of an identical text or by endorsement, at the latest by February 2004, and conflicting national standards shall be withdrawn at the latest by February 2004.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.

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 EU Directive(s).

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

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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)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

> **WARNING** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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.