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IRISH STANDARD

I.S. EN ISO 10993-10:2002

ICS 11.100

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**BIOLOGICAL EVALUATION OF MEDICAL
DEVICES - PART 10: TESTS FOR
IRRITATION AND DELAYED-TYPE
HYPERSENSITIVITY (ISO 10993-10:2002)**

*This Irish Standard was
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AMENDMENT

I.S. EN ISO 10993-10:2002/A1:2006

ICS 11.100.20

**BIOLOGICAL EVALUATION OF MEDICAL
DEVICES - PART 10: TESTS FOR IRRITATION
AND DELAYED-TYPE HYPERSENSITIVITY -
AMENDMENT 1 (ISO 10993-10:2002/AMD
1:2006)**

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English Version

**Biological evaluation of medical devices - Part 10: Tests for
irritation and delayed-type hypersensitivity - Amendment 1 (ISO
10993-10:2002/Amd 1:2006)**

Évaluation biologique des dispositifs médicaux - Partie 10:
Essais d'irritation et d'hypersensibilité retardée -
Amendement 1 (ISO 10993-10:2002/Amd 1:2006)

Biologische Beurteilung von Medizinprodukten - Teil 10:
Prüfungen auf Irritation und Allergien vom verzögerten Typ
- Änderung 1 (ISO 10993-10:2002/Amd 1:2006)

This amendment A1 modifies the European Standard EN ISO 10993-10:2002; it was approved by CEN on 7 July 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN ISO 10993-10:2002/A1:2006) 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of an identical text or by endorsement, at the latest by January 2007, and conflicting national standards shall be withdrawn at the latest by January 2007.

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 10993-10:2002 has been approved by CEN as EN ISO 10993-10:2002/A1:2006 without any modifications.

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