SLOVENSKI STANDARD

SIST EN ISO 10993-10:2003/A1:2006

01-oktober-2006

Biološko ovrednotenje medicinskih pripomočkov – 10. del: Preskusi draženja in zakasnjene preobčutljivosti – Dopolnilo 1 (ISO 10993-10:2002/Amd 1:2006)

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

Biologische Beurteilung von Medizinprodukten - Teil 10: Prüfungen auf Irritation und Allergien vom verzögerten Typ (ISO 10993-10:2002/A1:2006)

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

Ta slovenski standard je istoveten z: **EN ISO 10993-10:2002/A1:2006**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-10:2003/A1:2006 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-10:2002/A1

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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 (ISO 10993-10:2002/A1:2006)

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.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 10993-10:2002/A1:2006: E

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 10993-10:2002/Amd 1:2006 has been approved by CEN as EN ISO 10993-10:2002/A1:2006 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC and 90/385/EEC

This European Standard has been prepared under a mandate given to CEN to provide one means of conforming to Essential Requirements of the New Approach Directives 93/42/EEC Medical devices: General and 90/385/EEC Medical devices: Active implantable.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this International Standard confers, within the limits of the scope of this International Standard, a presumption of conformity with the relevant Essential Requirements of those Directives and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 10993-10

Second edition
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AMENDMENT 1
2006-07-15

Biological evaluation of medical devices —

Part 10:
Tests for irritation and delayed-type hypersensitivity

AMENDMENT 1

Évaluation biologique des dispositifs médicaux —

Partie 10: Essais d'irritation et d'hypersensibilité retardée

AMENDEMENT 1

Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

Amendment 1 to ISO 10993-10:2002 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.