SLOVENSKI

PREDSTANDARD

SIST EN ISO 10993-10:2003/oprA1:2005

april 2005

Biološko ovrednotenje medicinskih pripomočkov - 10. del: Preskusi draženja in občutljivosti (senzibilizacije) – Dopolnilo 1 (ISO 10993-10:2002/DAM 1:2005)

Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity - Amendment 1 (ISO 10993-10:2002/DAM 1:2005)

ICS 11.100.20

Referenčna številka
SIST EN ISO 10993-10:2003/oprA1:2005(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
EN ISO 10993-10:2002

prA1

February 2005

ICS

English version

Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity - Amendment 1 (ISO 10993-10:2002/DAM 1:2005)

Evaluation biologique des dispositifs médicaux - Partie 10: Essais d'irritation et d'hypersensibilité retardée - Amendement 1 (ISO 10993-10:2002/DAM 1:2005)

Biologische Beurteilung von Medizinprodukten - Teil 10: Prüfungen auf Irritation und Allergien vom verzögerten Typ - Änderung 1 (ISO 10993-10:2002/DAM 1:2004)

This draft amendment is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 206.

This draft amendment A1, if approved, will modify the European Standard EN ISO 10993-10:2002. If this draft becomes an amendment, 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.

This draft amendment was established by CEN 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.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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

Ref. No. EN ISO 10993-10:2002/prA1:2005: E

Foreword

This document (EN ISO 10993-10:2002/prA1:2005) 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 document is currently submitted to the parallel Enquiry.

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.

Endorsement notice

The text of ISO 10993-10:2002 has been approved by CEN as EN ISO 10993-10:2002/prA1:2005 without any modifications.

ANNEX ZA
(informative)

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

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC.

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 standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

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

DRAFT AMENDMENT ISO 10993-10:2002/DAmd 1

ISO/TC **194** Secretariat: **DIN**

Voting begins on: **2004-12-23** Voting terminates on: **2005-05-23**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

ICS 11.100.20

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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