SLOVENSKI STANDARD

SIST EN ISO 10993-12:2005

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Nadomeġļ a:

SIST EN ISO 10993-12:2000

Biologķko ovrednotenje medicinskih pripomoļ kov - 12. del: Priprava vzorcev in referenļ ni materiali (ISO 10993-12:2002)

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2002)

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien (ISO 10993-12:2002)

Evaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence (ISO 10993-12:2002)

Ta slovenski standard je istoveten z: **EN ISO 10993-12:2004**

ICS:

11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

SIST EN ISO 10993-12:2005 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-12

November 2004

ICS 11.100

Supersedes EN ISO 10993-12:1996

English version

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2002)

Evaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence (ISO 10993-12:2002)

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien (ISO 10993-12:2002)

This European Standard was approved by CEN on 27 October 2004.

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

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 10993-12:2004: E

Foreword

The text of the International Standard from Technical Committee ISO/TC 194 "Biological evaluation of medical devices" of the International Organization for Standardization (ISO) has been taken over as a European Standard by 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 May 2005, and conflicting national standards shall be withdrawn at the latest by May 2005.

This document supersedes EN ISO 10993-12:1996.

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

Endorsement notice

The text of ISO 10993-12:2002 has been approved by CEN as a European Standard, EN ISO 10993-12:2004, without any modifications.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 14971	2000	Medical devices – Application of risk management to medical devices	EN ISO 14971	2000

Annex ZB
(Informative)

Clauses of this International 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 93/42/EEC of 14 June 1993 concerning medical devices.

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

The following clauses of this standard are likely to support requirements of UE Directive 93/42/EEC of 14 June 1993 concerning medical devices

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

Table ZB.1 — Correspondence between this European Standard and EU Directives

Clauses/subclauses of this International Standard	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10, 11	7.1, 7.2, 7.3, 7.5	EN ISO 10993-12 'Biological evaluation of medical devices – Part 12: Sample preparation and reference materials' should be used in conjunction with th tests indicated in EN ISO 10993-1 'Biological evaluation of medical devices – Part 1: Evaluation and testing'.

INTERNATIONAL STANDARD

ISO 10993-12

Second edition
2002-12-15

Corrected version
2003-06-01

Biological evaluation of medical devices —

Part 12: Sample preparation and reference materials

Évaluation biologique des dispositifs médicaux —

Partie 12: Préparation des échantillons et matériaux de référence

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

ISO 10993-12 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-12:1996), which has been technically revised.

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

— *Part 1: Evaluation and testing*

— *Part 2: Animal welfare requirements*

— *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

— *Part 4: Selection of tests for interactions with blood*

— *Part 5: Tests for* in vitro *cytotoxicity*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 8: Selection and qualification of reference materials for biological tests*

— *Part 9: Framework for identification and quantification of potential degradation products*

— *Part 10: Tests for irritation and delayed-type hypersensitivity*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

— *Part 13: Identification and quantification of degradation products from polymeric medical devices*

— *Part 14: Identification and quantification of degradation products from ceramics*

— *Part 15: Identification and quantification of degradation products from metals and alloys*

— *Part 16: Toxicokinetic study design for degradation products and leachables*

— *Part 17: Establishment of allowable limits for leachable substances*

Future parts will deal with other relevant aspects of biological testing.

This corrected version of ISO 10993-12:2002 incorporates a correction in 10.3.4, in which a note clarifies use of other media in some countries.