SLOVENSKI STANDARD
SIST EN ISO 10993-12:2000

01-januar-2000

Biologķko ovrednotenje medicinskih pripomoļ kov - 12. del: Priprava vzorcev in referenļ ni materiali (ISO 10993-12:1996)

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:1996)

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien (ISO 10993-12:1996)

Evaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence (ISO 10993-12:1996)

Ta slovenski standard je istoveten z: **EN ISO 10993-12:1996**

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11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

SIST EN ISO 10993-12:2000 **en**

EUROPEAN STANDARD

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Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:1996)

Evaluation biologique des dispositifs médicaux - Partie 12: Préparation des échantillons et matériaux de référence (ISO 10993-12:1996)

Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien (ISO 10993-12:1996)

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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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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Foreword

The text of the International Standard ISO 10993-12:1996 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 NNI.

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of an identical text or by endorsement, at the latest by March 1997, and conflicting national standards shall be withdrawn at the latest by March 1997.

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(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10993-12:1996 was approved by CEN as a European Standard without any modification.

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).

Publication	Year	Title	EN/HD	Year
ISO 9000-1	1994	Quality management and quality assurance standards	EN ISO 9000-1	1994

INTERNATIONAL STANDARD

ISO 10993-12

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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

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Contents

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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.

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.

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

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 cytotoxicity: in vitro methods*

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

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 9: Degradation of materials related to biological testing* [Technical Report]

— *Part 10: Tests for irritation and sensitization*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

— *Part 13: Identification and quantification of degradation products from polymers*

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

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

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

— *Part 17: Glutaraldehyde and formaldehyde residues in industrially sterilized medical devices*

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

Annexes A, B, C and D of this part of ISO 10993 are for information only.

Introduction

This part of ISO 10993 gives guidance on methods of sample preparation and on the use of reference materials for use in biological evaluation. Because of the many different biological assay systems described in ISO 10993, the individual standards should be consulted to ascertain the appropriateness of these recommendations for a specific test system.

Sample preparation methods should consider both the biological evaluation methods and the materials being evaluated. Each biological test restricts selection of solid samples and extraction solvents or conditions by its own methodology.

This part of ISO 10993 is based on existing national and international specifications, regulations and standards wherever possible. It is open to regular review whenever new research work is presented to improve the state of scientific knowledge.