SLOVENSKI STANDARD

SIST EN ISO 10993-13:2000

01-januar-2000

Biologġko ovrednotenje medicinskih pripomoļ kov - 13. del: Prepoznavanje in ugotavljanje koliļ ine razgradnih produktov polimerov, iz katerih so izdelani medicinski pripomoļ ki (ISO 10993-13:1998)

Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)

Biologische Beurteilung von Medizinprodukten - Teil 13: Qualitativer und quantitativer Nachweis von Abbauprodukten in Medizinprodukten aus Polymeren (ISO 10993-13:1998)

Evaluation biologique des dispositifs médicaux - Partie 13: Identification et quantification de produits de dégradation de dispositifs médicaux à base de polymères (ISO 10993-13:1998)

Ta slovenski standard je istoveten z: EN ISO 10993-13:1998

ICS:

11.100.20	Biologġko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

SIST EN ISO 10993-13:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-13

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Descriptors:

English version

Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)

Evaluation biologique des dispositifs médicaux - Partie 13: Identification et quantification de produits de dégradation de dispositifs médicaux à base de polymères (ISO 10993-13:1998)

Biologische Beurteilung von Medizinprodukten - Teil 13: Qualitativer und quantitativer Nachweis von Abbauprodukten in Medizinprodukten aus Polymeren (ISO 10993-13:1998)

This European Standard was approved by CEN on 15 November 1998.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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

Ref. No. EN ISO 10993-13:1998 E

Foreword

The text of the International Standard ISO 10993-13:1998 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 May 1998, and conflicting national standards shall be withdrawn at the latest by May 1998.

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, Czech Republic, 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 10993-13:1998 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.

Publication	Year	Title	EN	Year
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997
ISO 10993-12	1996	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12	1996
ISO 10993-16	1997	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16	1997

INTERNATIONAL STANDARD

ISO 10993-13

First edition
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Biological evaluation of medical devices —

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

Évaluation biologique des dispositifs médicaux —
Partie 13: Identification et quantification de produits de dégradation de dispositifs médicaux à base de polymères

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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 10993-13 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: Framework for the identification and quantification of potential degradation products*

— *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 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*

Annex A of this part of ISO 10993 is for information only.

Introduction

This part of ISO 10993 was developed from ISO/TR 10993-9. Degradation products covered by this standard are formed primarily by chemical bond scission due to hydrolytic and/or oxidative processes in an aqueous environment. It is recognized that additional biological factors, such as enzymes, other proteins and cellular activity, can alter the rate and nature of degradation.

It should be kept in mind that a polymeric device may contain residuals and leachables such as monomers, oligomers, solvents, catalysts, additives, fillers and processing aids. These components which, if present, may interfere with the identification and quantification of the degradation products, need to be considered and accounted for. It should be recognized that residual monomers may generate the same degradation products as the polymer itself.

The identified and quantified degradation products form the basis for biological evaluation in accordance with ISO 10993-1, for risk assessment in accordance with ISO 14538 and, if appropriate, for toxicokinetic studies in accordance with ISO 10993-16.