SLOVENSKI STANDARD
SIST EN ISO 10993-9:2000

01-januar-2000

Biologķko ovrednotenje medicinskih pripomoļ kov - 9. del: Okvirni sistem za prepoznavanje in ugotavljanje koliļ ine morebitnih razgradnih produktov (ISO 10993-9:1999)

Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)

Biologische Beurteilung von Medizinprodukten - Teil 9: Rahmen zur Identifizierung und Quantifizierung von möglichen Abbauprodukten (ISO 10993-9:1999)

Evaluation biologique des dispositifs médicaux - Partie 9: Cadre pour l'identification et la quantification des produits potentiels de dégradation (ISO 10993-9:1999)

Ta slovenski standard je istoveten z: **EN ISO 10993-9:1999**

ICS:

11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English version

Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)

Evaluation biologique des dispositifs médicaux - Partie 9: Cadre pour l'identification et la quantification des produits potentiels de dégradation (ISO 10993-9:1999)

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This European Standard was approved by CEN on 1 March 1999.

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 10993-9:1999 E

Foreword

The text of the International Standard ISO 10993-9:1999 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 September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.

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.

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 10993-9:1999 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 10993-9

First edition
1999-03-01

Biological evaluation of medical devices —

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

Évaluation biologique des dispositifs médicaux —
Partie 9: Cadre pour l'identification et la quantification des produits potentiels de dégradation

Reference number
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Contents

Page

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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 3.

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 10993-9 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This first edition cancels and replaces the first edition of ISO/TR 10993-9:1994, 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 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 polymers*

— *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 18: Chemical characterization.*

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

Annex A forms a normative part of this part of ISO 10993. Annex B is for information only.

Introduction

This part of 10993 is intended to present the general principles on which the specific material investigations to identify and quantify degradation products described in ISO 10993-13 (polymers), ISO 10993-14 (ceramics) and ISO 10993-15 (metals and alloys) are based.

Information obtained from these studies is intended to be used in the biological evaluations described in the remaining parts of ISO 10993.

The materials used to construct medical devices may form degradation products when exposed to the biological environment, and these products may behave differently than the bulk material in the body.

Degradation products can be generated in different ways, either mechanically (by relative motion between two or more different components), by fatigue loading, as a result of fracture and/or by release from the medical device due to interactions with the environment, or combinations thereof.

Mechanical wear causes mostly particulate debris, whereas the release of substances from surfaces due to leaching, chemical breakdown of structures or corrosion can lead to free ions or to different kinds of reaction products in the form of organic or inorganic compounds.

The degradation products may be either reactive, or stable and without biochemical reaction with their environment. Accumulations of substantial quantities of stable degradation products may, however, have physical effects on the surrounding tissues. Degradation products may remain at the location of their generation or may be transported within the biological environment by various mechanisms.

The level of biological tolerability of degradation products depends on their nature and concentration, and should be primarily assessed through clinical experience and focused studies. For theoretically possible, new and/or unknown degradation products, relevant testing is necessary. For well-described and clinically accepted degradation products, no further investigation may be necessary.

Biological evaluation of medical devices —

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

1 Scope

This part of ISO 10993 provides general principles for the systematic evaluation of the potential and observed biodegradation of medical devices and for the design and performance of biodegradation studies.

This part of ISO 10993 is not applicable to:

a) viable-tissue engineered products;

b) methodologies for the generation of degradation products by mechanical processes. Methodologies for the production of this type of degradation product are described in specific product standards, where available;

c) leachable components which are not degradation products.

Where product standards provide applicable product-specific methodologies for the identification and quantification of degradation products, those standards shall be considered as alternatives.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*.

3 Terms and definitions

For the purposes of this part of ISO 10993, the terms and definitions given in ISO 10993-1 and the following apply.

3.1
degradation
decomposition of a material