

SLOVENSKI STANDARD

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Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)

Biologische Beurteilung von Medizinprodukten - Teil 16: Entwurf und Auslegung toxikokinetischer Untersuchungen hinsichtlich Abbauprodukten und Extrakten (ISO 10993-16:1997)

Évaluation biologique des dispositifs médicaux - Partie 16 : Conception des études toxicocinétiques des produits de dégradation et des substances relargables (ISO 10993-16:1997)

Ta slovenski standard je istoveten z: EN ISO 10993-16:2009

ICS:

11.100.20	Óä z\[\Äç!^â}[ç}b {^äää•\äç]ä[[{\[ç	Biological evaluation of medical devices
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-16

April 2009

ICS 11.100.20

Supersedes EN ISO 10993-16:1997

English Version

**Biological evaluation of medical devices - Part 16: Toxicokinetic
study design for degradation products and leachables (ISO
10993-16:1997)**

Évaluation biologique des dispositifs médicaux - Partie 16:
Conception des études toxicocinétiques des produits de
dégradation et des substances relargables (ISO 10993-
16:1997)

Biologische Beurteilung von Medizinprodukten - Teil 16:
Entwurf und Auslegung toxikokinetischer Untersuchungen
hinsichtlich Abbauprodukten und Extrakten (ISO 10993-
16:1997)

This European Standard was approved by CEN on 12 April 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 10993-16:1997 has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10993-16:2009 by Technical Committee CEN/TC 206 "Biological evaluation of medical 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10993-16:1997.

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 Directives 93/42/EEC on Medical Devices and 90/385/EEC on Active Implantable Medical Devices.

For relationship with the EU Directives, see informative Annexes ZA and 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10993-16:1997 has been approved by CEN as a EN ISO 10993-16:2009 without any modification.

Annex ZA (informative)

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

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 on medical devices.

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 clauses of this standard given in table ZA 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.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5 & Annex A	Annex I: 7.1, 7.2, 7.5	

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

Annex ZB (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

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 90/385/EEC on active implantable medical devices.

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 clauses of this standard given in table ZB 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.

Table ZB — Correspondence between this European Standard and Directive 90/385/EEC on active implantable medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4, 5 & Annex A	Annex I 9	

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

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INTERNATIONAL STANDARD

ISO
10993-16

First edition
1997-09-01

Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables

*Évaluation biologique des dispositifs médicaux —
Partie 16: Conception des études toxicocinétiques des produits de
dégradation et des substances relargables*

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ISO 10993-16:1997(E)

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International Organization for Standardization

Case postale 56 • CH-1211 Genève 20 • Switzerland

Internet central@iso.ch

X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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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 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 [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 metals and alloys
- Part 16: Toxicokinetic study design for degradation products and leachables

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

Annex A forms an integral part of this part of ISO 10993. Annex B is for information only.