SLOVENSKI STANDARD
SIST EN ISO 10993-16:2010

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Nadomešča:
SIST EN ISO 10993-16:2009

Biološko ovrednotenje medicinskih pripomočkov - 16. del: Načrt toksikokinetičnih raziskav razgradnih produktov in izlužnin (ISO 10993-16:2010)

Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)

Biologische Beurteilung von Medizinprodukten - Teil 16: Entwurf und Auslegung toxikokinetischer Untersuchungen hinsichtlich Abbauprodukten und Extrakten (ISO 10993-16:2010)

Évaluation biologique des dispositifs médicaux - Partie 16: Conception des études toxicocinétiques des produits de dégradation et des substances relargables (ISO 10993-16:2010)

Ta slovenski standard je istoveten z: **EN ISO 10993-16:2010**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 10993-16:2010 **en**

EUROPEAN STANDARD

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English Version

Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)

Évaluation biologique des dispositifs médicaux - Partie 16: Conception des études toxicocinétiques des produits de dégradation et des substances relargables (ISO 10993-16:2010)

Biologische Beurteilung von Medizinprodukten - Teil 16: Entwurf und Auslegung toxikenitischer Untersuchungen hinsichtlich Abbauprodukten und herauslösbaren Bestandteilen (ISO 10993-16:2010)

This European Standard was approved by CEN on 20 January 2010.

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 10993-16:2010) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration 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 August 2010, and conflicting national standards shall be withdrawn at the latest by August 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 10993-16:2009.

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.

For relationship with EU Directives, see informative Annex ZA and ZB, which are integral parts 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, Croatia, 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 10993-16:2010 has been approved by CEN as a EN ISO 10993-16:2010 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 Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this International Standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, Annex A	7.1, 7.2, 7.5	These relevant Essential Requirements are only partly addressed in this International Standard

GENERAL NOTE — Presumption of conformity depends on also complying with all relevant clauses/subclauses of ISO 10993-1.

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 International Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this International Standard given in Table ZB.1 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.1 — Correspondence between this European Standard and Directive 90/385/EEC on Active Implantable Medical Devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4, 5, Annex A	9 (First and second indents only)	The first and second indents of this relevant Essential Requirement are only partly addressed in this International Standard

GENERAL NOTE — Presumption of conformity depends on also complying with all relevant clauses/subclauses of ISO 10993-1.

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

INTERNATIONAL STANDARD

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Évaluation biologique des dispositifs médicaux —

Partie 16: Conception des études toxicocinétiques des produits de dégradation et des substances relargables

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