

SLOVENSKI STANDARD

SIST EN ISO 10993-13:2010

01-december-2010

Nadomešča:

SIST EN ISO 10993-13:2009

Biolško ovrednotenje medicinskih pripomočkov - 13. del: Prepoznavanje in ugotavljanje količine razgradnih produktov polimerov, iz katerih so izdelani medicinski pripomočki (ISO 10993-13:2010)

Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)

iTeh STANDARD PREVIEW

Biologische Beurteilung von Medizinprodukten - Teil 13: Qualitativer und quantitativer Nachweis von Abbauprodukten in Medizinprodukten aus Kunststoff (ISO 10993-13:2010)

[SIST EN ISO 10993-13:2010](http://standards.iTeh.si/SIST/EN/ISO/10993-13:2010)

Évaluation biologique des dispositifs médicaux - Partie 13: Identification et quantification de produits de dégradation de dispositifs médicaux à base de polymères (ISO 10993-13:2010)

Ta slovenski standard je istoveten z: EN ISO 10993-13:2010

ICS:

11.100.20	Biolško ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-13

June 2010

ICS 11.100.20

Supersedes EN ISO 10993-13:2009

English Version

**Biological evaluation of medical devices - Part 13: Identification
and quantification of degradation products from polymeric
medical devices (ISO 10993-13:2010)**

Évaluation biologique des dispositifs médicaux - Partie 13:
Identification et quantification de produits de dégradation
de dispositifs médicaux à base de polymères (ISO 10993-
13:2010)

Biologische Beurteilung von Medizinprodukten - Teil 13:
Qualitativer und quantitativer Nachweis von
Abbauprodukten in Medizinprodukten aus Polymeren (ISO
10993-13:2010)

This European Standard was approved by CEN on 5 June 2010.

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, 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 United Kingdom.



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Foreword

This document (EN ISO 10993-13:2010) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with 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 December 2010, and conflicting national standards shall be withdrawn at the latest by December 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 10993-13:2009.

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.

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Endorsement notice

The text of ISO 10993-13:2010 has been approved by CEN as a EN ISO 10993-13:2010 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 European 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 European Standard given in Table ZA.1 confers, within the limits of the scope of this International 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)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC on Medical devices	Qualifying remarks/notes
4, 5 and 6	7.1 and 7.5	These relevant Essential Requirements are only partly addressed in this standard.

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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 European 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 European 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 European Standard given in Table ZB.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 ZB.1 — Correspondence between this European Standard and Directive 90/385/EEC on Active Implantable Medical Devices

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC on Active Implantable Medical Devices	Qualifying remarks/notes
4, 5 and 6	9 (first and second indents only)	The first and second indents of this relevant Essential Requirement are only partly addressed in this 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 European Standard.

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INTERNATIONAL
STANDARD

ISO
10993-13

Second edition
2010-06-15

**Biological evaluation of medical
devices —**

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

iTeh STANDARD PREVIEW

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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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