

**Meditiiniseadmete bioloogiline hindamine. Osa 13:
Polümeersetest meditsiiniseadmetest pärit
mittetäisväärtuslike saaduste kuuluvuse ja koguse
kindlakstegemine**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10993-13:2009 sisaldab Euroopa standardi EN ISO 10993-13:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 29.04.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 10993-13:2009 consists of the English text of the European standard EN ISO 10993-13:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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Võtmesõnad: bioloogilised testid, halvenemine, kindlaksmääramine, meditsiiniaparatuur, meditsiiniseadmed, plasttooted, polümeerid, testimine

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English Version

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

Évaluation 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 12 April 2009.

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Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of ISO 10993-13:1998 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 10993-13:2009 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 10993-13:1998.

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 10993-13:1998 has been approved by CEN as a EN ISO 10993-13:2009 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, 6	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, 6	Annex I : 9	

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 Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

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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.

Biological evaluation of medical devices —

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

1 Scope

This part of ISO 10993 provides guidance on general requirements for the design of tests for identifying and quantifying degradation products from finished polymeric medical devices ready for clinical use.

This part of ISO 10993 describes two test methods to generate degradation products, an accelerated degradation test as a screening method and a real-time degradation test. For materials which are intended to polymerize *in situ*, the set or cured polymer is used for testing. The data generated are used in the biological evaluation of the polymer.

This part of ISO 10993 considers only those degradation products generated by a chemical alteration of the finished polymeric device. It is not applicable to degradation of the device induced during its intended use by mechanical stress, wear or electromagnetic radiation.

The biological activity of the debris and soluble degradation products is not addressed in this part of ISO 10993, but should be evaluated according to the principles of ISO 10993-1 and ISO 14538.

Because of the wide range of polymeric materials used in medical devices, no specific analytical techniques are identified or given preference. No specific requirements for acceptable levels of degradation products are provided in this part of ISO 10993.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

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

ISO 10993-9:—¹⁾, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*.

ISO 10993-12:1996, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*.

¹⁾ To be published.

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

ISO 13781:1997, *Poly(L-lactide) resins and fabricated forms for surgical implants — In vitro degradation testing*.

ISO 14538:—¹⁾ *Biological evaluation of medical devices — Establishment of permissible limits for sterilization and process residues using health-based risk assessment*.

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