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Meditsiiniseadmete bioloogiline hindamine. Osa 9: Potentsiaalsete lagusaaduste identifitseerimise ja kvantifitseerimise raamistik

Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10993-9:2009 sisaldab Euroopa standardi EN ISO 10993-9:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10993-9:2009 consists of the English text of the European standard EN ISO 10993-9:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	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.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 20.05.2009.	Date of Availability of the European standard text 20.05.2009.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-9

May 2009

ICS 11.100.20

Supersedes EN ISO 10993-9:1999

English Version

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

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

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

This European Standard was approved by CEN on 28 April 2009.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 10993-9:2009: E

Foreword

The text of ISO 10993-9:1999 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 10993-9:2009 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 November 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 10993-9:1999.

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 EU Directives, see informative Annex ZA and ZB, which is an integral part of this document.

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Endorsement notice

The text of ISO 10993-9:1999 has been approved by CEN as a EN ISO 10993-9:2009 without any modification.

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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.

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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	The test methods do not include pass/fail criteria

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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.

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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