Meditsiiniseadmete bioloogiline hindamine. Osa 18. Materjalide keemiline iseloomustus

Biological evaluation of medical devices - Part 18: Chemical characterization of materials

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10993-18:2009 sisaldab Euroopa standardi EN ISO 10993-18:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10993-18:2009 consists of the English text of the European standard EN ISO 10993-18:2009.
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 29.04.2009.	Date of Availability of the European standard text 29.04.2009.
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Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)

Évaluation biologique des dispositifs médicaux - Partie 18: Caractérisation chimique des matériaux (ISO 10993-18:2005)

Biologische Beurteilung von Medizinprodukten - Teil 18: Chemische Charakterisierung von Werkstoffen (ISO 10993-18:2005)

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

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Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 10993-18:2005 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 10993-18:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 10993-18:2005.

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 10993-18:2005 has been approved by CEN as a EN ISO 10993-18:2009 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
5, 6, 7, 8 & 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
5, 6, 7, 8, & Annex A	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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Introduction

ISO 10993-1 provides a framework for a structured programme of assessment for the evaluation of biological safety. Clause 3 of ISO 10993-1:2003 states that in the selection of materials to be used for device manufacture the first consideration should be fitness for purpose. This should have regard to the characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological and mechanical properties. This information is necessary prior to any biological evaluation. Subclause 7.2 of ISO 10993-1:2003 notes that the continuing acceptability of a biological evaluation is an aspect of a quality management system.

Also ISO 14971 points out that a toxicological risk analysis should take account of the chemical nature of the materials.

The requirements specified in this document are intended to yield the following information, which will be of value in predicting the biological response of the materials:

— The chemical composition of the materials used in the manufacturing process including processing additives and residues e.g. trace chemicals, cleaning, disinfection and testing agents, acids and caustic substances.

— The characterization of materials to be used in the production of medical devices, as well as in devices in their final form.

— Identification of the materials of construction of the medical device.

— The potential of medical device materials to release substances or breakdown products due to the manufacturing process.

— Changes in the materials of construction, which result from changes in the manufacturing process or insufficient control of the manufacturing process.

The compositional characteristics of the materials of manufacture are mainly under the control of the suppliers of these materials. However other characteristics are chiefly influenced by the requirements to be met by the finished medical device as well as the processes used by the medical device manufacturer.

Biological evaluation of medical devices —

Part 18:
Chemical characterization of materials

1 Scope

This part of ISO 10993 describes a framework for the identification of a material and the identification and quantification of its chemical constituents. The chemical characterization information generated can be used for a range of important applications, for example:

— As part of an assessment of the overall biological safety of a medical device (ISO 10993-1 and 14971).

— Measurement of the level of a leachable substance in a medical device in order to allow the assessment of compliance with the allowable limit derived for that substance from health based risk assessment (ISO 10993-17).

— Judging equivalence of a proposed material to a clinically established material.

— Judging equivalence of a final device to a prototype device to check the relevance of data on the latter to be used to support the assessment of the former.

— Screening of potential new materials for suitability in a medical device for a proposed clinical application.

This part of ISO 10993 does not address the identification or quantification of degradation products, which is covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.

The ISO 10993 series of standards is applicable when the material or device comes into contact with the body directly or indirectly (see 4.2.1 of ISO 10993-1:2003).

This part of ISO 10993 is intended for suppliers of materials and manufacturers of medical devices, when carrying out a biological safety assessment.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*