Meditsiiniseadmete bioloogiline hindamine. Osa 14: Keraamika lagusaaduste identifitseerimine ja kvantifitseerimine

Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10993-14:2002 sisaldab Euroopa standardi EN ISO 10993-14:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 16.05.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10993-14:2002 consists of the English text of the European standard EN ISO 10993-14:2001. This document is endorsed on 16.05.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard specifies two methods of obtaining solutions of degradation products from ceramics (including glasses) for the purposes of quantification.	**Scope:** This standard specifies two methods of obtaining solutions of degradation products from ceramics (including glasses) for the purposes of quantification.

ICS 11.100

Võtmesõnad: biological tests, ceramics, decomposition, decomposition products, deterioration, evaluations, identification, medical equipment, medical products, quantification, testing

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English version

Biological evaluation of medical devices

Part 14: Identification and quantification of degradation products from ceramics
(ISO 10993-14 : 2001)

Evaluation biologique des dispositifs médicaux – Partie 14: Identification et quantification des produits de dégradation des céramiques
(ISO 10993-14 : 2001)

Biologische Beurteilung von Medizinprodukten – Teil 14: Qualitativer und quantitativer Nachweis von keramischen Abbauprodukten
(ISO 10993-14 : 2001)

This European Standard was approved by CEN on 2001-10-14.

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 Management Centre or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

International Standard

ISO 10993-14 : 2001 Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics,

which was prepared by ISO/TC 194 'Biological evaluation of medical devices' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 206 'Biocompatibility of medical and dental materials and devices', the Secretariat of which is held by NEN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by May 2002 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10993-14 : 2001 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZB (normative).

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Introduction

This part of ISO 10993 consists of two tests for the biological evaluation of medical devices: an extreme solution test and a simulation solution test. The extreme solution test is developed as a worst-case environment and the simulation test is developed as a very common environment.

Degradation products covered by this part of ISO 10993 are formed primarily by dissolution in an aqueous environment. It is recognized that additional biological factors such as enzymes and proteins can alter the rate of degradation. Degradation by such outside factors is not addressed in this part of ISO 10993.

It should be kept in mind that a ceramic device might have extraneous chemical phases and/or elements in extremely minor amounts. Whilst these components might not be named in the original specification, they can often be suspected by the relationship that the material in question has to other materials and the expected history of the material's processing.

Once identified and quantified, the chemical composition of the degradation products form the basis for risk assessment and, if appropriate, biological safety studies according to the principles of ISO 10993-1.

1 Scope

This part of ISO 10993 specifies two methods of obtaining solutions of degradation products from ceramics (including glasses) for the purposes of quantification. It also gives guidance on the analysis of these solutions in order to identify the degradation products. Because of the generalized nature of this part of ISO 10993, product specific standards, when available, that address degradation product formation under more relevant conditions of use, should be considered first.

This part of ISO 10993 considers only those degradation products generated by a chemical dissociation of ceramics during *in vitro* testing. No degradation induced by mechanical stress or external energy is covered. It is noted that while ISO 6872 and ISO 9693 cover chemical degradation tests, they do not address the analysis of degradation products.

Because of the range of ceramics used in medical devices and the different requirements for accuracy and precision of the results, no specific analytical techniques are identified. Further, this part of ISO 10993 provides no specific requirements for acceptable levels of degradation products.

Although these materials are intended for biomedical applications, the biological activity of these degradation products is not addressed in this part of ISO 10993.

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 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

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

ISO 5017, *Dense shaped refractory products — Determination of bulk density, apparent porosity and true porosity*

ISO 6474, *Implants for surgery — Ceramic materials based on high purity alumina*

ISO 6872:1995, *Dental ceramic*

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