Meditsiiniseadmete bioloogiline hindamine. Osa 17: Aine eraldumise lubatud piirmäärade kehtestamine (ISO 10993-17:2002)

Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10993-17:2003 sisaldab Euroopa standardi EN ISO 10993-17:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 15.04.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10993-17:2003 consists of the English text of the European standard EN ISO 10993-17:2002. This document is endorsed on 15.04.2003 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 part of ISO 10993 specifies a method for the determination of allowable limits for substances leachable from medical devices	**Scope:** This part of ISO 10993 specifies a method for the determination of allowable limits for substances leachable from medical devices

ICS 11.100

Võtmesõnad: determination, establishment, evaluations, health hazards, identification, limits (mathematics), mathematics, medical devices, medical equipment, medical products, metals, methods, quantification, residues, risk analysis, soluble, testing, toxicological testing

EUROPEAN STANDARD
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English version

Biological evaluation of medical devices

Part 17: Establishment of allowable limits for leachable substances
(ISO 10993-17 : 2002)

Évaluation biologique des dispositifs médicaux – Partie 17: Établissement des limites admissibles des substances relargables
(ISO 10993-17 : 2002)

Biologische Beurteilung von Medizinprodukten – Teil 17: Nachweis zulässiger Grenzwerte für herauslösbare Bestandteile (ISO 10993-17 : 2002)

This European Standard was approved by CEN on 2002-10-09.

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.

The European Standards exist 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 Management Centre has the same status as the official versions.

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CEN

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

Management Centre: rue de Stassart 36, B-1050 Brussels

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Foreword

International Standard

ISO 10993-17 : 2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances,

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 June 2003 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, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10993-17 : 2002 was approved by CEN as a European Standard without any modification.

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

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Introduction

The determination of the suitability of a medical device for a particular use involves balancing any identified risks with the clinical benefit to the patient associated with its use. Among the risks to be considered are those arising from exposure to leachable substances arising from medical devices.

Risks associated with exposure to hazardous leachable substances are managed by identifying the leachable substances, quantifying the associated risks and limiting exposure within tolerable levels. This part of ISO 10993 provides a method by which maximum tolerable levels can be calculated from available data on health risks. Allowable limits may be based upon health risks that can be systemic or local, immediate or delayed, and range in severity from minor localized adverse effects to life-threatening risks. These allowable limits are intended to be derived, using this part of ISO 10993, by toxicologists or other knowledgeable and experienced individuals, capable of making informed decisions based upon scientific data and a knowledge of medical devices.

The allowable limits derived may be used by anyone. In addition to use by ISO, other standards-developing organizations, government agencies, regulatory bodies, and other users for setting allowable limits as standards or regulations, manufacturers and processors may use the allowable limits derived to optimize processes and aid in the choice of materials in order to protect patient health. Where risks associated with exposure to particular leachable substances are unacceptable, this part of ISO 10993 can be used to qualify alternative materials or processes.

1 Scope

This part of ISO 10993 specifies a method for the determination of allowable limits for substances leachable from medical devices. It is intended for use in deriving standards and estimating appropriate limits where standards do not exist. It describes a systematic process through which identified risks arising from toxicologically hazardous substances present in medical devices can be quantified.

This part of ISO 10993 is not applicable to devices that have no patient contact (e.g. *in vitro* diagnostic devices).

Exposure to a particular chemical substance may arise from sources other than the device, such as food, water or air. This part of ISO 10993 does not address the potential for exposure from such sources.

2 Normative reference

The following normative document contains 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 edition of the normative document 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, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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
allowable limit
AL
largest amount of a leachable substance that is deemed acceptable on a daily basis, when taken into the body through exposure to a medical device

NOTE Allowable limits are expressed in dose to the patient for each applicable exposure period. The units used are mass per unit time, e.g. milligrams per day. These doses represent tolerable risks for medical devices under the circumstances of intended use.

3.2
benefit factor
BF
numerical factor that takes into account the health benefit from use of the medical device(s) containing the leachable substance in question