Meditsiiniseadmete bioloogiline hindamine. Osa 2: Nõuded loomade heaolule

Biological evaluation of medical devices - Part 2: Animal welfare requirements

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10993-2:1999 sisaldab Euroopa standardi EN ISO 10993-2:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10993-2:1999 consists of the English text of the European standard EN ISO 10993-2:1998. This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi ISO 10993 käesolev osa esitab miinimumnõuded loomade kasutamisele bioloogilises testimises.	**Scope:**

ICS 11.100

Võtmesõnad: bioloogilised testid, hambaraviaparatuur, kirurgiline instrumentaarium, kirurgilised implantaadid, laboriloomad, meditsiiniaparatuur, testimine

EUROPEAN STANDARD
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EN ISO 10993-2

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Descriptors: Medical equipment, animal welfare.

English version

Biological evaluation of medical devices

Part 2: Animal welfare requirements
(ISO 10993-2 : 1992)

Évaluation biologique des dispositifs médicaux – Partie 2: Exigences concernant la protection des animaux (ISO 10993-2 : 1992)

Biologische Beurteilung von Medizinprodukten – Teil 2: Tierschutzbestimmungen (ISO 10993-2 : 1992)

This European Standard was approved by CEN on 1998-01-01.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of 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.

CEN

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

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Foreword

International Standard

ISO 10993-2 : 1992 Biological evaluation of medical devices – Part 2: Animal welfare requirements,

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 IBN, 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 August 1998 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 10993-2 : 1992 was approved by CEN as a European Standard without any modification.

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

Contents

Introduction

The protection of humans is the primary goal of the ISO 10993 series of standards. A second equally important goal is to ensure animal welfare and to minimize the number and exposure of the laboratory animals.

This part of ISO 10993 was developed to ensure the welfare of animals used in biological evaluation testing. Therefore, minimum requirements for the care and use of animals are stated.

A list of international documents concerning the care and handling of animals in biomedical research is given in annex A for information.

1 Scope

This part of ISO 10993 specifies minimum requirements for the use of animals in biological testing.

This part of ISO 10993 is also intended

a) to establish guidelines which allow the scientist to respect life in general;

b) to reduce the number of animal experiments and the number of animals used in experiments, among other ways by optimization of those performed;

c) to minimize suffering and maintain the quality of life of the animals used in the experiments.

This part of ISO 10993 applies to the experimentation performed on vertebrates. It does not apply to experimentation performed on less differentiated animals; nor does it apply to that part of the experimental work performed on isolated tissues and organs.

This part of ISO 10993 also makes recommendations concerned with the aim of reducing the number of animals used for biocompatibility testing and when possible abolishing animal experiments in this area.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 10993. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

3 Definitions

For the purposes of this part of ISO 10993, the definitions given in ISO 10993-1 and the following definitions apply.

3.1 animal: Any live non-human vertebrate, excluding foetal or embryonic forms, unless otherwise qualified.

3.2 experimental animal: Animal used or to be used in experiments.

3.3 bred animal: Animal specially bred for use in experiments in facilities accredited by, or registered with, the competent authority.

3.4 animal experiment: Any use of an animal for scientific purposes which may cause it pain, anxiety, suffering, distress or lasting harm, excluding the least painful methods accepted in modern veterinary or