Meditsiiniseadmete bioloogiline hindamine. Osa 11: Katsed süsteemse toksilisuse hindamiseks

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10993-11:2009 sisaldab Euroopa standardi EN ISO 10993-11:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10993-11:2009 consists of the English text of the European standard EN ISO 10993-11:2009.
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.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.100.20

Võtmesõnad: bioloogilised testid, hambaraviaparatuur, hambaravimaterjalid, kindlaksmääramine, kirurgiline instrumentaarium, kirurgilised implantaadid, meditsiiniaparatuur, testimine, toksilisus

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-11

April 2009

ICS 11.100.20

Supersedes EN ISO 10993-11:2006

English Version

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)

Évaluation biologique des dispositifs médicaux - Partie 11: Essais de toxicité systémique (ISO 10993-11:2006)

Biologische Beurteilung von Medizinprodukten - Teil 11: Prüfungen auf systemische Toxizität (ISO 10993-11:2006)

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

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Ref. No. EN ISO 10993-11:2009: E

Foreword

The text of ISO 10993-11:2006 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 10993-11:2009 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 10993-11:2006.

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 are integral parts 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 10993-11:2006 has been approved by CEN as a EN ISO 10993-11:2009 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
4, 5, 6	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
4, 5, 6	Annex I : 9	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword ... iv

Introduction ... vi

1 Scope ... 1

2 Normative references ... 1

3 Terms and definitions ... 1

4 General considerations ... 2
4.1 General ... 2
4.2 Selection of animal species ... 3
4.3 Animal status ... 3
4.4 Animal care and husbandry ... 3
4.5 Size and number of groups ... 3
4.6 Route of exposure ... 4
4.7 Sample preparation ... 4
4.8 Dosing ... 5
4.9 Body weight and food/water consumption ... 6
4.10 Clinical observations ... 6
4.11 Clinical pathology ... 6
4.12 Anatomic pathology ... 7
4.13 Study designs ... 7
4.14 Quality of investigation ... 7

5 Acute systemic toxicity ... 7
5.1 General ... 7
5.2 Study design ... 8
5.3 Evaluation criteria ... 9
5.4 Final report ... 10

6 Repeated exposure systemic toxicity (subacute, subchronic and chronic systemic toxicity) ... 11
6.1 General ... 11
6.2 Study design ... 12
6.3 Evaluation criteria ... 14
6.4 Final report ... 15

Annex A (informative) **Routes of administration** ... 16

Annex B (informative) **Dosage volumes** ... 18

Annex C (informative) **Common clinical signs and observations** ... 19

Annex D (informative) **Suggested haematology, clinical chemistry and urinalysis measurements** ... 20

Annex E (informative) **Suggested organ list for histopathological evaluation** ... 22

Annex F (informative) **Information on material-mediated pyrogens** ... 24

Bibliography ... 26

Introduction

Systemic toxicity is a potential adverse effect of the use of medical devices. Generalized effects, as well as organ and organ system effects can result from absorption, distribution and metabolism of leachates from the device or its materials to parts of the body with which they are not in direct contact. This part of ISO 10993 addresses the evaluation of generalized systemic toxicity, not specific target organ or organ system toxicity, even though these effects may result from the systemic absorption and distribution of toxicants.

Because of the broad range of medical devices, and their materials and intended uses, this part of ISO 10993 is not overly prescriptive. Whilst it addresses specific methodological aspects to be considered in the design of systemic toxicity tests, proper study design must be uniquely tailored to the nature of the device's materials and its intended clinical application.

Other elements of this part of ISO 10993 are prescriptive in nature, including those aspects that address compliance with good laboratory practices and elements for inclusion in reporting.

While some systemic toxicity tests (e.g. long term implantation or dermal toxicity studies) can be designed to study systemic effects as well as local, carcinogenic or reproductive effects, this document focuses only on those aspects of such studies, which are intended to address systemic effects. Studies which are intended to address other toxicological endpoints are addressed in ISO 10993-3, ISO 10993-6, ISO 10993-10 and ISO/TS 10993-20.

Pyrogenicity (see Annex F) represents an additional systemic effect which has historically been included in this part of ISO 10993. However, efforts are being taken to address pyrogenicity in a dedicated, stand-alone standard.

Finally, toxicology is an imperfect science. The outcome of any single test should not be the sole basis for making a determination of whether a device is safe for its intended use.

Biological evaluation of medical devices —

Part 11:
Tests for systemic toxicity

1 Scope

This part of ISO 10993 specifies requirements and gives guidance on procedures to be followed in the evaluation of the potential for medical device materials to cause adverse systemic reactions.

2 Normative references

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

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

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*