Biological evaluation of medical devices - Part 1: Evaluation and testing

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10993-1:2009 sisaldab Euroopa standardi EN ISO 10993-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10993-1:2009 consists of the English text of the European standard EN ISO 10993-1:2009.
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 10.06.2009.	Date of Availability of the European standard text 10.06.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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EN ISO 10993-1

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Supersedes EN ISO 10993-1:2003

English Version

Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)

Évaluation biologique des dispositifs médicaux - Partie 1: Evaluation et essais (ISO 10993-1:2003)

Biologische Beurteilung von Medizinprodukten Teil 1: Beurteilung und Prüfung (ISO 10993-1:2003)

This European Standard was approved by CEN on 23 May 2009.

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 CEN Management Centre or to any CEN member.

This European Standard exists 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 CEN Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 10993-1:2003 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 10993-1:2009 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 December 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 10993-1:2003.

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 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 10993-1:2003 has been approved by CEN as a EN ISO 10993-1:2009 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
3, 4, 5, 6, 7	Annex I: 7.1, 7.2, 7.5	The presumption of conformity depends on applying the other parts of the EN ISO 10993 series that are relevant

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
3, 4, 5, 6, 7	Annex I : 9	The presumption of conformity depends on applying the other parts of the EN ISO 10993 series that are relevant

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

This part of ISO 10993 is a combination/harmonization of numerous international and national standards and guidelines concerning the biological evaluation of medical devices. It is intended to be the overall guidance document for the selection of tests enabling evaluation of biological responses relevant to the safety of medical devices and materials.

The role of this part of ISO 10993 is to serve as a framework in which to plan such a biological evaluation which minimizes the number and exposure of test animals.

The protection of humans is the primary goal of ISO 10993.

The appropriate selection and interpretation of biological evaluation tests requires an understanding of the rationale behind such testing. An informative rationale for the use of this part of ISO 10993 is provided in Annex A. Annex B contains a flow chart to aid in the systematic approach to the biological evaluation of medical devices. A bibliography is given at the end of the text.

Biological evaluation of medical devices —

Part 1:
Evaluation and testing

1 Scope

This part of ISO 10993 describes

a) the general principles governing the biological evaluation of medical devices;

b) the categorization of devices based on the nature and duration of their contact with the body;

c) the selection of appropriate tests.

This part of ISO 10993 does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body, nor does it cover biological hazards arising from any mechanical failure.

NOTE Other parts of ISO 10993 cover specific tests (see also the rationale in A.2).

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
medical device
any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

NOTE 1 Devices are different from drugs, and their biological evaluation requires a different approach.

NOTE 2 Use of the term “medical device” includes dental devices.

2.2
material
any synthetic or natural polymer, metal, alloy, ceramic or other nonviable substance, including tissue rendered nonviable, used as a medical device or any part thereof