



SLOVENSKI STANDARD SIST EN ISO 10993-2:2006

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Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2006)

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Biologische Beurteilung von Medizinprodukten - Teil 2: Tierschutzbestimmungen (ISO 10993-2:2006)

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Évaluation biologique des dispositifs médicaux - Partie 2: Exigences relatives a la protection des animaux (ISO 10993-2:2006)

Ta slovenski standard je istoveten z: EN ISO 10993-2:2006

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-2

July 2006

ICS 11.100.20

Supersedes EN ISO 10993-2:1998

English Version

**Biological evaluation of medical devices - Part 2: Animal welfare
requirements (ISO 10993-2:2006)**

Évaluation biologique des dispositifs médicaux - Partie 2:
Exigences relatives à la protection des animaux (ISO
10993-2:2006)

Biologische Beurteilung von Medizinprodukten - Teil 2:
Tierschutzbestimmungen (ISO 10993-2:2006)

This European Standard was approved by CEN on 14 July 2006.

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.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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 United Kingdom.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

EN ISO 10993-2:2006 (E)**Foreword**

This document (EN ISO 10993-2:2006) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 "Biocompatibility of medical and dental materials and 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 January 2007, and conflicting national standards shall be withdrawn at the latest by January 2007.

This document supersedes EN ISO 10993-2:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 United Kingdom.

Endorsement notice

The text of ISO 10993-2:2006 has been approved by CEN as EN ISO 10993-2:2006 without any modifications.

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INTERNATIONAL
STANDARD

ISO
10993-2

Second edition
2006-07-15

**Biological evaluation of medical
devices —**

**Part 2:
Animal welfare requirements**

Évaluation biologique des dispositifs médicaux —

Partie 2: Exigences relatives à la protection des animaux

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Reference number
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ISO 10993-2:2006(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10993-2 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-2:1992), which has been technically revised.

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ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

- *Part 1: Evaluation and testing* [SIST EN ISO 10993-2:2006
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- *Part 2: Animal welfare requirements*
- *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *Part 4: Selection of tests for interactions with blood*
- *Part 5: Tests for in vitro cytotoxicity*
- *Part 6: Tests for local effects after implantation*
- *Part 7: Ethylene oxide sterilization residuals*
- *Part 9: Framework for identification and quantification of potential degradation products*
- *Part 10: Tests for irritation and delayed-type hypersensitivity*
- *Part 11: Tests for systemic toxicity*
- *Part 12: Sample preparation and reference materials*
- *Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *Part 14: Identification and quantification of degradation products from ceramics*
- *Part 15: Identification and quantification of degradation products from metals and alloys*

- *Part 16: Toxicokinetic study design for degradation products and leachables*
- *Part 17: Establishment of allowable limits for leachable substances*
- *Part 18: Chemical characterization of materials*
- *Part 19: Physico-chemical, morphological and topographical characterization of materials*
- *Part 20: Principles and methods for immunotoxicology testing of medical devices*

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ISO 10993-2:2006(E)**Introduction**

The goal of the ISO 10993 series of International Standards is the protection of humans in the context of the use of medical devices.

This part of ISO 10993 supports the goal of the ISO 10993 series by promoting good science through paying proper regard to maximizing the use of scientifically sound non-animal tests and by ensuring that those animal tests performed to evaluate the biological properties of materials used in medical devices are conducted humanely according to recognized ethical and scientific principles.

The application of such humane experimental techniques, including high standards of animal care and accommodation, both help to ensure the scientific validity of safety testing and enhance the welfare of the animals used.

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Biological evaluation of medical devices —

Part 2: Animal welfare requirements

1 Scope

This part of ISO 10993 is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or that of the medical devices themselves. It specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices.

It also makes recommendations and offers guidance intended to facilitate future further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests.

It applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices.

It does not apply to tests performed on invertebrate animals and other lower forms; nor (other than with respect to provisions relating to species, source, health status, and care and accommodation) does it apply to testing performed on isolated tissues and organs taken from vertebrate animals that have been euthanized.

2 Normative references

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

ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

3 Terms and definitions

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

3.1

alternative method

any test method that replaces an animal test, reduces the numbers of animals used, or refines the procedures applied

3.2

animal

any live non-human vertebrate, excluding immature forms during the first half of gestation or incubation