SLOVENSKI STANDARD
SIST EN ISO 10993-2:2000

01-januar-2000

Biologķko ovrednotenje medicinskih pripomoļ kov - 2. del: Zahteve za varstvo ģivali (ISO 10993-2:1992)

Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:1992)

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

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

Ta slovenski standard je istoveten z: **EN ISO 10993-2:1998**

ICS:

11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

SIST EN ISO 10993-2:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10993-2

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English version

Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:1992)

Evaluation 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 1 January 1998.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 194 "Biological evaluation of medical devices" of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 206 "Biocompatibility of medical and dental materials and devices", the secretariat of which is held by NNI.

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

Part 1:	Guidance on selection of tests
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 cytotoxicity: *in vitro* methods
Part 6:	Tests for local effects after implantation
Part 7:	Ethylene oxide sterilization residuals
Part 9:	Degradation of materials related to biological testing
Part 10:	Tests for irritation and sensitization
Part 11:	Tests for systemic toxicity
Part 12:	Sample preparation and reference materials
Part 13:	Identification and quantification of degradation products from polymers
Part 14:	Identification and quantification of degradation products from ceramics
Part 15:	Identification and quantification of degradation products from coated and uncoated metals and alloys
Part 16:	Toxicokinetic study design for degradation products and leachables
Part 17:	Glutaraldehyde and formaldehyde residues in industrially sterilized medical devices

Future parts will deal with other relevant aspects of biological testing.

Annex A of this part of ISO 10993 is for information only.

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, 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 Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 10993-1	1992	Biological evaluation of medical devices - Part 1: Guidance on selection of tests	EN 30993-1	1994

INTERNATIONAL STANDARD

ISO 10993-2

First edition
1992-12-15

Biological evaluation of medical devices —

Part 2:
Animal welfare requirements

Évaluation biologique des dispositifs médicaux —

Partie 2: Exigences concernant la protection des animaux

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Contents

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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.

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.

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

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

— *Part 1: Guidance on selection of tests*

— *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 cytotoxicity: in vitro methods*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 8: Clinical investigation*

— *Part 9: Degradation of materials related to biological testing*

— *Part 10: Tests for irritation and sensitization*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

Future parts will deal with other relevant aspects of biological testing.

Annex A of this part of ISO 10993 is for information only.