SLOVENSKI STANDARD
SIST EN ISO 10993-10:2000

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Biologķko ovrednotenje medicinskih pripomoļ kov - 10. del: Preskusi draģenja in obļ utljivosti (senzibilizacije) (ISO 10993-10:1995)

Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization (ISO 10993-10:1995)

Biologische Beurteilung von Medizinprodukten - Teil 10: Prüfungen auf Irritation und Sensibilisierung (ISO 10993-10:1995)

Evaluation biologique des dispositifs médicaux - Partie 10: Essais d'irritation et de sensibilisation (ISO 10993-10:1995)

Ta slovenski standard je istoveten z: **EN ISO 10993-10:1995**

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11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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Descriptors: medical equipment, surgical equipment, surgical instruments, surgical implants, dental equipment, dental instruments, tests, biological tests, skin irritation

English version

Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization (ISO 10993-10:1995)

Evaluation biologique des dispositifs médicaux - Partie 10: Essais d'irritation et de sensibilisation (ISO 10993-10:1995)

Biologische Beurteilung von Medizinprodukten - Teil 10: Prüfungen auf Irritation und Sensibilisierung (ISO 10993-10:1995)

This European Standard was approved by CEN on 1995-12-06. 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.

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CEN

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 ISO/TC 194 "Biological evaluation of medical devices" of the International Organization dor Standardization (ISO) has been taken over as a European Standard by the Technical Committee CEN/TC 206 "Biocompatibility of medical and dental materials and devices".

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 June 1996, and conflicting national standards shall be withdrawn at the latest by June 1996.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

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
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:	General guidance on 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.

This part of ISO 10993 is a harmonization of numerous standards and guidlines, including BS 5736, OECD Guidelines, U.S. Pharmacopeia and the European Pharmacopoeia. It is intended to be the overall guidance document for the selection and conduct of tests enabling evaluation of irritation and sensitization responses relevant to material and device safety.

Annexes A, B and C form an integral part of this part of ISO 10993. Annexes D, E and F are for information only.

Endorsement notice

The text of the International Standard ISO 10993-10 : 1995 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications 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 (including amendments).

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

INTERNATIONAL STANDARD

ISO 10993-10

First edition
1995-03-15

Biological evaluation of medical devices —

Part 10:
Tests for irritation and sensitization

Évaluation biologique des dispositifs médicaux —

Partie 10: Essais d'irritation et de sensibilisation

Reference number
ISO 10993-10:1995(E)

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 10993-10 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 9: Degradation of materials related to biological testing* [Technical Report]

— *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: General guidance on 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.

This part of ISO 10993 is a harmonization of numerous standards and guidelines, including BS 5736, OECD Guidelines, U.S. Pharmacopeia and the European Pharmacopoeia. It is intended to be the overall guidance document for the selection and conduct of tests enabling evaluation of irritation and senitization responses relevant to material and device safety.

Annexes A, B and C form an integral part of this part of ISO 10993. Annexes D, E and F are for information only.

Introduction

This part of ISO 10993 assesses possible contact hazards from device-released chemicals that may produce skin and mucosal irritation, eye irritation, and delayed contact sensitization.

Some materials that are included in these devices have been tested, and their skin or mucosal irritation or sensitization potential has been documented. Other materials and their chemical components have not been tested and may act differently when exposed to biological tissues. It is incumbent upon the manufacturer to evaluate each device for its human toxic potential prior to marketing.

Traditionally, small animal tests are performed prior to human testing to help predict human response. More recently, *in vitro* tests have been added as an alternative. Despite progress and considerable effort in this direction, a review of findings suggests that currently no satisfactory *in vitro* test has been devised to eliminate the requirement for *in vivo* testing. Where appropriate, the preliminary use of *in vitro* methods is encouraged as screening tests prior to animal testing. In order to reduce the number of animals used, these standards use a step-wise approach with review and analysis of test results at each stage.

It is incumbent upon the investigator to conduct these studies using good scientific laboratory practices, complying with regulations related to animal welfare. Since the number of animals is restricted, the data obtained may be insufficient to warrant the application of statistics.

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Biological evaluation of medical devices —

Part 10:
Tests for irritation and sensitization

1 Scope

This part of ISO 10993 describes test methods:

a) to evaluate the potential of devices and their constituent materials to produce irritation; and

b) to evaluate the potential of devices and their constituent materials to produce sensitization.

These test methods are recommended for most categories of device and mode of body contact given in ISO 10993-1. Of the tests listed, those appropriate to the end use of the device are to be selected. Guidance is also given for the preparation of materials specifically in relation to the above tests.

NOTE 1 Guidance on the conduct of supplementary tests which may be required specifically for use in the oral, rectal, penile and vaginal areas is given in annex D.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. At the time of publication, the editions indicated were 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 editions of the standards 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.*

ISO 10993-12:—[1], *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.*

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 (allergic contact) sensitization; delayed contact hypersensitivity: Allergic response involving immunological systems that have been activated by prior exposure.

3.2 irritation: Localized inflammatory response to single, repeated or continuous application of the test substance, without involvement of an immunological mechanism.

3.3 oedema: Swelling due to abnormal infiltration of fluid into the tissues.

3.4 erythema: Reddening of the skin or mucous membrane.

3.5 eschar: Scab or discoloured slough of skin.

3.6 corrosion: Production of irreversible tissue damage at the site of contact with the skin following the application of a test substance.

1) To be published.