SLOVENSKI STANDARD
SIST EN 30993-3:2000

01-januar-2000

Biološko ovrednotenje medicinskih pripomočkov - 3. del: Preskusi genske toksičnosti, kancerogenosti in toksičnosti za razmnoževanje (ISO 10993-3:1992)

Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:1992)

Biologische Beurteilung von Medizinprodukten - Teil 3: Prüfungen auf Gentoxizität, Karzinogenität und Reproduktionstoxizität (ISO 10993-3:1992)

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Essais biologiques des matériaux médicaux - Partie 3: Essais concernant la génotoxicité, la cancérogénicité et la toxicité sur la reproduction (ISO 10993-3:1992)

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Ta slovenski standard je istoveten z: **EN 30993-3:1993**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN 30993-3:2000 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 30993-3

December 1993

UDC 615.46/47.076:616.314:541.657

Descriptors: Medical equipment, dental equipment, bioassay, evaluation, toxicity, genetics, carcinogens, reproduction

English version

Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicty and reproductive toxicity (ISO10993-3:1992)

Essais biologiques des matériaux médicaux - Partie 3: Essais concernant la génotoxicité, la cancerogenicité et la toxicité sur la reproduction (ISO 10993-3:1992)

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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

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SIST EN 30993-3:2000

FOREWORD

This European Standard is the endorsement of ISO 10 993-3:1992. Endorsement of ISO 10 993-3 was recommended by CEN/TC 206 "Biocompatibility of medical and dental materials and devices" under whose competence this European Standard will henceforth fall.

ISO 10 993 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

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Future parts will deal with other relevant aspects of biological testing. Annex A of this part of ISO 10 993 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 1994-06, and conflicting national standards shall be withdrawn at the latest by 1994-06.

The Standard was approved and in accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

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

Endorsement notice

The text of the International Standard ISO 10 993-3:1992 was approved by CEN as a European Standard without any modification.

SIST EN 30993-3:2000

INTERNATIONAL STANDARD

ISO 10993-3

First edition
1992-12-15

Biological evaluation of medical devices —

Part 3:
Tests for genotoxicity, carcinogenicity and reproductive toxicity

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Évaluation biologique des dispositifs médicaux —
Partie 3: Essais concernant la génotoxicité, la cancérogénicité et la toxicité sur la reproduction

SIST EN 30993-3:2000
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Reference number
ISO 10993-3:1992(E)

SIST EN 30993-3:2000

Contents

iTeh STANDARD PREVIEW
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SIST EN 30993-3:2000
https://standards.iteh.ai/catalog/standards/sist/22151144-da73-47db-9515-d670642961ea/sist-en-30993-3-2000

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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.

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International Standard ISO 10993-3 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

SIST EN 30993-3:2000
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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.

SIST EN 30993-3:2000

Introduction

The basis for biocompatibility evaluation of medical devices is often empirical and driven by the relevant concerns for human safety. Not all test methods for the assessment of genotoxicity, carcinogenicity or reproductive toxicity are equally well developed, nor is their validity well established for the testing of medical devices.

Significant issues in test sample size and preparation, scientific understanding of disease processes and test validation can be cited as limitations of available methods. For example the biological significance of solid state carcinogenesis is poorly understood. It is expected that ongoing scientific and medical advances will alter our understanding and approaches to these important toxicity test methods. At the time the document was prepared, the test methods proposed were those most acceptable. Sound scientific alternatives to the proposed testing should be acceptable insofar as they address relevant matters of safety assessment.

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In the selection of tests needed to evaluate a particular device, there is no substitute for a careful assessment of expected human uses and potential interactions of the device with various biological systems. These considerations will be particularly important in such areas as reproductive and developmental toxicology.

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https://standards.iteh.ai/catalog/standards/sist/22151144-da73-47db-9515-d67964296 1ca/sist-en-30993-3-2000

This part of ISO 10993 presents test methods for the detection of specific biological hazards, and therefore maximum test sensitivity is required. The interpretation of findings and implications for human health effects are beyond the scope of this part of ISO 10993. Because of the multitude of possible outcomes and the importance of such factors as extent of exposure, species differences and mechanical or physical considerations, risk assessment has to be performed on a case-by-case basis.

SIST EN 30993-3:2000

Biological evaluation of medical devices —

Part 3:
Tests for genotoxicity, carcinogenicity and reproductive toxicity

1 Scope

This part of ISO 10993 specifies tests for the following biological aspects:

— genotoxicity,

— carcinogenicity, and

— reproductive and developmental toxicity.

These are relevant in the biological evaluation of some categories of medical devices (see note 1). Guidance on selection of tests is provided in ISO 10993-1. Where the need for the evaluation of the potential for genotoxicity, carcinogenicity or reproductive toxicity has been identified, they should be evaluated in accordance with this part of ISO 10993.

Most tests included in this part of the International Standard refer to the OECD guidelines for testing of chemicals. Reference to these tests is made by the term "OECD guideline(s)" followed by the appropriate test number(s).

At the time of testing, these tests are to be performed according to current OECD guidelines.

NOTE 1 The term "devices" corresponds to the definition given in ISO 10993-1 and covers materials, as well as dental materials and devices. The definition is in accordance with the CEN standard document.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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.

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SIST EN 30993-3:2000
https://standards.iteh.ai/catalog/standards/sist/22151144-da73-47db-9515-d670642961ea/sist-en-30993-3-2000

ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 10993-2:—[1], *Biological evaluation of medical devices — Part 2: Animal welfare requirements.*

***OECD Guidelines for testing of chemicals* — Selected assays**

— *In vitro* genotoxicity tests

471 *Genetic Toxicology:* Salmonella typhimurium, *Reverse Mutation Assay.*

472 *Genetic Toxicology:* Escherichia coli, *Reverse Mutation Assay.*

473 *Genetic Toxicology:* In vitro *Mammalian Cytogenetic Test.*

476 *Genetic Toxicology:* In vitro *Mammalian Cell Gene Mutation Test.*

479 *Genetic Toxicology:* In vitro *Sister Chromatid Exchange Assay in Mammalian Cells.*

480 *Genetic Toxicology:* Saccharomyces cerevisiae, *Gene Mutation Assay.*

481 *Genetic Toxicology:* Saccharomyces cerevisiae, *Mitotic Recombination Assay.*

1) To be published.