SLOVENSKI STANDARD
oSIST prEN ISO 10993-3:2013

01-april-2013

Biološko vrednotenje medicinskih pripomočkov - 3. del: Preskusi genske toksičnosti, kancerogenosti in toksičnosti za razmnoževanje (ISO/DIS 10993-3:2013)

Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO/DIS 10993-3:2013)

Biologische Beurteilung von Medizinprodukten - Teil 3: Prüfungen auf Gentoxizität, Karzinogenität und Reproduktionstoxizität (ISO/DIS 10993-3:2013)

Évaluation biologique des dispositifs médicaux - Partie 3: Essais concernant la génotoxicité, la cancérogénicité et la toxicité sur la reproduction (ISO/DIS 10993-3:2013)

Ta slovenski standard je istoveten z: **FprEN ISO 10993-3 rev**

ICS:

11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

oSIST prEN ISO 10993-3:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Will supersede EN ISO 10993-3:2009

English Version

Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO/FDIS 10993-3:2013)

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This draft European Standard is submitted to CEN members for second parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 206.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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Foreword

This document (prEN ISO 10993-3:2013) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological evaluation of medical devices” the secretariat of which is held by NEN.

This document is currently submitted to the second parallel Enquiry.

This document will supersede EN ISO 10993-3:2009.

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 Directive(s).

Endorsement notice

The text of ISO/DIS 10993-3:2013 has been approved by CEN as prEN ISO 10993-3:2013 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 10993-3.2

ISO/TC **194** Secretariat: **DIN**

Voting begins on **2013-02-14** Voting terminates on **2013-04-14**

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Biological evaluation of medical devices —

Part 3:
Tests for genotoxicity, carcinogenicity and reproductive toxicity

Évaluation biologique des dispositifs médicaux —

Partie 3: Essais concernant la génotoxicité, la cancérogénicité et la toxicité sur la reproduction

[Revision of second edition (ISO 10993-3:2003)]

ICS 11.100.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

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 10993-3 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices* and by Technical Committee CEN/TC 206, *Biological evaluation of medical devices* in collaboration.

This third edition cancels and replaces the second edition (EN ISO 10993:2003), which has been technically revised.

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

— Part 1: *Evaluation and testing within a risk management procedure*

— 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: *Method for the establishment of allowable limits for leachable substances*

— Part 18: *Chemical characterization of materials*

— Part 19: *Physico-chemical, morphological and topographical characterization of materials [Technical specification]*

— Part 20: *Principles and methods for immunotoxicology testing of medical devices [Technical specification]*

Introduction

The basis for biological evaluation of medical devices is often empirical and driven by the relevant concerns for human safety. The risk of serious and irreversible effects, such as cancer or second generation abnormalities, is of particular public concern. It is inherent in the provision of safe medical devices that such risks be minimised to the greatest extent feasible. The assessment of mutagenic, carcinogenic and reproductive hazards is an essential component of the control of these risks. 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 with 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 improve our understanding of and approaches to these important toxicity test methods. At the time this document was prepared, the test methods proposed were those most acceptable. Scientifically sound alternatives to the proposed testing may be acceptable insofar as they address relevant matters of safety assessment.

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

This part of ISO 10993 presents test methods for the detection of specific biological hazards, and strategies for the selection of tests, where appropriate, that will assist in hazard identification. Testing is not always necessary or helpful in hazard identification but, where it is appropriate, it is important that maximum test sensitivity is achieved.

The interpretation of findings and their 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 factors such as extent of exposure, species differences and mechanical or physical considerations, risk assessment has to be performed on a case-by-case basis.