SLOVENSKI STANDARD
SIST EN ISO 10993-1:2000

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Biologķko ovrednotenje medicinskih pripomoļ kov - 1. del: Ocena in preskusi (ISO 10993-1:1997)

Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)

Biologische Beurteilung von Medizinprodukten Teil 1: Beurteilung und Prüfung (ISO 10993-1:1997)

Evaluation biologique des dispositifs médicaux - Partie 1: Evaluation et essais (ISO 10993-1:1997)

Ta slovenski standard je istoveten z: **EN ISO 10993-1:1997**

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EUROPEAN STANDARD

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English version

Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)

Evaluation biologique des dispositifs médicaux - Partie 1: Evaluation et essais (ISO 10993-1:1997)

This European Standard was approved by CEN on 21 November 1997.

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.

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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 ISO 10993-1:1997 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 NNI.

This European Standard supersedes EN 30993-1:1994.

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 EU Directive(s).

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 1998, and conflicting national standards shall be withdrawn at the latest by June 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 10993-1:1997 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 10993-1

Second edition
1997-12-15

Biological evaluation of medical devices —

Part 1:
Evaluation and testing

Évaluation biologique des dispositifs médicaux —

Partie 1: Évaluation et essais

Reference number
ISO 10993-1:1997(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 10993-1 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-1:1992), 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*

— *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: Framework for the identification and quantification of potential degradation products*

— *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 metals and alloys*

— *Part 16: Toxicokinetic study design for degradation products and leachables*

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

Annexes A, B and C of this part of ISO 10993 are for information only.

Introduction

This part of ISO 10993 is a combination/harmonization of numerous International and national Standards and guidelines concerning the biological evaluation of medical devices. It is intended to be the overall guidance document for the selection of tests enabling evaluation of biological responses relevant to the safety of medical devices and materials.

The role of this part of ISO 10993 is to serve as a framework in which to plan such a biological evaluation which minimizes the number and exposure of test animals.

The protection of humans is the primary goal of ISO 10993.

The appropriate selection and interpretation of biological evaluation tests requires an understanding of the rationale behind such testing. An informative rationale for the use of this part of ISO 10993 is provided in annex A. Annex B contains a flow chart to aid in the systematic approach to the biological evaluation of medical devices. Annex C contains an informative bibliography.

Biological evaluation of medical devices —

Part 1:
Evaluation and testing

1 Scope

This part of ISO 10993 describes

a) the general principles governing the biological evaluation of medical devices;

b) the categorization of devices based on the nature and duration of their contact with the body;

c) the selection of appropriate tests.

This part of ISO 10993 does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body, nor does it cover biological hazards arising from any mechanical failure. Other parts of ISO 10993 cover specific tests as indicated in the foreword. (See also the rationale in A.2.)

2 Definitions

For the purposes of this part of ISO 10993, the following definitions apply.

2.1 medical device: Any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception.

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTES

1 Devices are different from drugs, and their biological evaluation requires a different approach.

2 Use of the term “medical device” includes dental devices.

2.2 material: Any synthetic or natural polymer, metal, alloy, ceramic, or other nonviable substance, including tissue rendered nonviable, used as a medical device or any part thereof.

2.3 final product: Medical device in its “as-used” state.