SLOVENSKI STANDARD
SIST EN 30993-6:2000

01-januar-2000

Biologķko ovrednotenje medicinskih pripomoļ kov - 6. del: Preskusi, povezani z lokalnimi uļ inki po implantaciji (ISO 10993-6:1994)

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:1994)

Biologische Beurteilung von Medizinprodukten - Teil 6: Prüfungen auf lokale Effekte nach Implantationen (ISO 10993-6:1994)

Evaluation biologique des dispositifs médicaux - Partie 6: Essais concernant les effets locaux apres implantation (ISO 10993-6:1994)

Ta slovenski standard je istoveten z: **EN 30993-6:1994**

ICS:

11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

SIST EN 30993-6:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 30993-6

October 1994

ICS 11.020

Descriptors: medical equipment, surgical equipment, surgical implants, dental equipment, dental materials, tests, biological tests, determination, acceptability

English version

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:1994)

Evaluation biologique des dispositifs médicaux - Partie 6: Essais concernant les effets locaux après implantation (ISO 10993-6:1994)

Biologische Beurteilung von Medizinprodukten - Teil 6: Prüfungen auf lokale Effekte nach Implantation (ISO 10993-6:1994)

This European Standard was approved by CEN on 1994-10-19. 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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Ref. No. EN 30993-6:1994 E

Foreword

This European Standard has been taken over by the Technical Committee CEN/TC 206 "Biocompatibilty of medical and dental materials and devices" from the work of ISO/TC 194 "Biological evaluation of medical devices" of the International Organization for Standardization (ISO).

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 April 1995, and conflicting national standards shall be withdrawn at the latest by April 1995.

According to 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, United Kingdom.

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

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

Annex A, B and C of this part of ISO 10 993 are for information only.

Endorsement notice

The text of the International Standard ISO 10993-6:1994 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	Year
ISO 10993-1	1992	Biological evaluation of medical devices - Part 1: Guidance on selection of tests	EN 30993-1	1994

INTERNATIONAL STANDARD

ISO 10993-6

First edition
1994-07-15

Biological evaluation of medical devices —

Part 6:
Tests for local effects after implantation

Évaluation biologique des dispositifs médicaux —

Partie 6: Essais concernant les effets locaux après implantation

Reference number
ISO 10993-6:1994(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

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 10993-6 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 from medical devices*

— *Part 17: Glutaraldehyde and formaldehyde residues in industrially sterilized medical devices*

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 International Standard gives methods of biological testing of medical and dental materials and devices, and their evaluation in regard to their biocompatibility.

ISO 10993-1 offers a guide for selection of methods for biological testing. The intention is to reduce animal tests to the justifiable minimum (see ISO 10993-2). A search of the literature precedes any testing, as data concerning the biological safety of the candidate material could be available.

The test methods described in this part of ISO 10993 are based on established implantation tests. This part of ISO 10993 describes animal tests for the study of local effects after implantation. The use of *in vivo* implantation techniques for characterizing the biological response of tissues to materials allows for the assessment of such materials not achieved by other procedures.

These test methods may not be appropriate for all types of medical devices. The user is cautioned to consider the appropriateness of the method in view of the materials being tested, their potential applications, and the recommendations contained in ISO 10993-1.

ISO/TC 194 appreciates any information for the further development of this part of ISO 10993.