SLOVENSKI STANDARD
SIST EN ISO 10993-15:2001

01-november-2001

Biologķko ovrednotenje medicinskih pripomoļ kov - 15. del: Identifikacija in ugotavljanje koliļ ine razgradnih produktov iz kovin in zlitin (ISO 10993-15:2000)

Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)

Biologische Beurteilung von Medizinprodukten - Teil 15: Qualitativer und quantitativer Nachweis von Abbauprodukten aus Metallen und Legierungen (ISO 10993-15:2000)

Evaluation biologique des dispositifs médicaux - Partie 15: Identification et quantification des produits de dégradation issus des métaux et alliages (ISO 10993-15:2000)

Ta slovenski standard je istoveten z: **EN ISO 10993-15:2000**

ICS:

11.100.20	Biologķko ovrednotenje medicinskih pripomoļ kov	Biological evaluation of medical devices

SIST EN ISO 10993-15:2001 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10993-15

December 2000

ICS 11.100

English version

Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)

Evaluation biologique des dispositifs médicaux - Partie 15: Identification et quantification des produits de dégradation issus des métaux et alliages (ISO 10993-15:2000)

Biologische Beurteilung von Medizinprodukten - Teil 15: Qualitativer und quantitativer Nachweis von Abbauprodukten aus Metallen und Legierungen (ISO 10993-15:2000)

This European Standard was approved by CEN on 1 December 2000.

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 Management Centre 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 Management Centre has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 10993-15:2000 E

Foreword

Corrected 2001-03-08

The text of the International Standard ISO 10993-15:2000 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 NEN.

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 2001, and conflicting national standards shall be withdrawn at the latest by June 2001.

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).

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 10993-15:2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards 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).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 3696	1987	Water for analytical laboratory use — Specification and test methods	EN ISO 3696	1995
ISO 8044	1999	Corrosion of metals and alloys — Basic terms and definitions	EN ISO 8044	1999
ISO 10993-1	1997	Biological evaluation of medical devices — Part 1: Evaluation and testing	EN ISO 10993-1	1997
ISO 10993-9	1999	Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products	EN ISO 10993-9	1999
ISO 10993-12	1996	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	EN ISO 10993-12	1996
ISO 10993-13	1998	Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices	EN ISO 10993-13	1998
ISO 10993-16	1997	Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16	1997

INTERNATIONAL STANDARD

ISO 10993-15

First edition
2000-12-01

Corrected and reprinted
2001-04-01

Biological evaluation of medical devices —

Part 15: Identification and quantification of degradation products from metals and alloys

Évaluation biologique des dispositifs médicaux —

Partie 15: Identification et quantification des produits de dégradation issus des métaux et alliages

Reference number
ISO 10993-15:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

Foreword iv

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Degradation test methods 2
4.1 General 2
4.2 Prerequisites 3

5 Reagent and sample preparation 3
5.1 Sample documentation 3
5.2 Test solution (electrolyte) 3
5.3 Preparation of test samples 3

6 Electrochemical tests 4
6.1 Apparatus 4
6.2 Sample preparation 4
6.3 Test conditions 5
6.4 Potentiodynamic measurements 5
6.5 Potentiostatic measurements 5

7 Immersion test 5
7.1 Apparatus 5
7.2 Sample preparation 7
7.3 Immersion test procedure 7

8 Analysis 8

9 Test report 8

Annex A (informative) Schematic diagram of the electrochemical measuring circuit 9

Annex B (informative) Schematic drawing of an electrolytic cell 10

Annex C (informative) Examples of alternative electrolytes for the electrochemical tests 11

Bibliography 12

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 3.

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 part of ISO 10993 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 10993-15 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: 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* in vitro *cytotoxicity*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 8: Selection and qualification of reference materials for biological tests*

— *Part 9: Framework for identification and quantification of potential degradation products*

— *Part 10: Tests for irritation and delayed-type hypersensitiviy*

— *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: Establishment of allowable limits for leachable substances using health-based risk assessment*

— *Part 18: Chemical characterization of materials*

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.