SLOVENSKI STANDARD
SIST EN ISO 7405:2000

01-januar-2000

Dentistry - Preclinical evaluation of biocompatability of medical devices used in dentistry - Test methods for dental materials (ISO 7405:1997)

Dentistry - Preclinical evaluation of biocompatability of medical devices used in dentistry - Test methods for dental materials (ISO 7405:1997)

Zahnheilkunde - Präklinische Beurteilung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten - Prüfverfahren für zahnärztliche Werkstoffe (ISO 7405:1997)

Art dentaire - Evaluation préclinique de la biocompatibilité des dispositifs médicaux utilisées en art dentaire - Méthodes d'essai des matériaux dentaires (ISO 7405:1997)

Ta slovenski standard je istoveten z: **EN ISO 7405:1997**

ICS:

11.060.01	Zobozdravstvo na splošno	Dentistry in general
11.100.20	Biološko ovrednotenje medicinskih pripomočkov	Biological evaluation of medical devices

SIST EN ISO 7405:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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English version

Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry - Test methods for dental materials (ISO 7405:1997)

Art dentaire - Evaluation préclinique de la biocompatibilité des dispositifs médicaux utilisées en art dentaire - Méthodes d'essai des matériaux dentaires (ISO 7405:1997)

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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

Foreword

The text of the International Standard ISO 7405:1997 has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by February 1998, and conflicting national standards shall be withdrawn at the latest by February 1998.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 7405:1997 was approved by CEN as a European Standard without any modification.

CORRECTED 1997-12-04

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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.

Publication	Year	Title	EN	Year
ISO 1942-2	1989	Dental vocabulary - Part 2: Dental materials	EN 21942-2	1992
ISO 10993-1	1992	Biological evaluation of medical devices - Part 1: Guidance on selection of tests	EN 30993-1	1994
ISO 10993-3	1992	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN 30993-3	1993
ISO 10993-5	1992	Biological evaluation of medical devices - Part 5: Tests for cytotoxicity - in vitro methods	EN 30993-5	1994
ISO 10993-6	1994	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	EN 30993-6	1994
ISO 10993-10	1995	Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization	EN ISO 10993-10	1995
ISO 10993-11	1993	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11	1995
ISO 10993-12	1996	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12	1996
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 7405

First edition
1997-08-15

Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials

Art dentaire — Évaluation préclinique de la biocompatibilité des dispositifs médicaux utilisés en art dentaire — Méthodes d'essai des matériaux dentaires

Reference number
ISO 7405:1997(E)

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 7405 was prepared by Technical Committee ISO/TC 106, *Dentistry*, in conjunction with the World Dental Federation (FDI).

This first edition cancels and replaces ISO/TR 7405:1984, which has been technically revised (see Introduction) and converted into an International Standard.

Annexes A, B and C of this International Standard are for information only.

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Introduction

This International Standard concerns the preclinical testing of dental materials in medical devices used in dentistry. It has been developed from and supersedes ISO/TR 7405:1984, *Biological evaluation of dental materials*, and its supplements, and should be read in conjunction with the ISO 10993, *Biological evaluation of medical devices*, series of standards. This International Standard differs from ISO/TR 7405 in several important ways. Firstly, it contains details of test methods applicable only to dental materials. Many test methods previously included in ISO/TR 7405 are now included in the ISO 10993 series of standards and details of them have therefore been excluded from this standard. Secondly, only test methods for which the members of the committee considered there was sufficient published data have been included. Thirdly, in recommending test methods, the need to minimize the use of animals was given a high priority.

The annexes are informative, to encourage the development of *in vitro* and *in vivo* test methods which will further reduce the use of animals in the preclinical evaluation of the biocompatibility of medical devices used in dentistry.

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Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials

1 Scope

This International Standard specifies methods for the evaluation of biological effects of dental materials. It includes testing of pharmacological agents that are an integral part of the device under test.

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.

ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials*

ISO 10993-1:—[1], *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

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

ISO 10993-5:1992, *Biological evaluation of medical devices — Part 5: Tests for cytotoxicity:* in vitro *methods*

ISO 10993-6:1994, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO/TR 10993-9:1994, *Biological evaluation of medical devices — Part 9: Degradation of materials related to biological testing*

ISO 10993-10:1995, *Biological evaluation of medical devices — Part 10: Tests for irritation and sensitization*

ISO 10993-11:1993, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 10993-12:—[2], *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-13:—[2], *Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymers*

ISO 10993-14:— [2], *Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics*

ISO 10993-15:— [2], *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from coated and uncoated metals and alloys*

ISO 10993-16:— [2], *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables.*

1) To be published. (Revision of ISO 10993-1:1992)

2) To be published