Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 7405:2009 sisaldab Euroopa standardi EN ISO 7405:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7405:2009 consists of the English text of the European standard EN ISO 7405:2008.
Standard on kinnitatud Eesti Standardikeskuse 29.01.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 29.01.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.12.2008.	Date of Availability of the European standard text 15.12.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.060.10, 11.100

Võtmesõnad: bioloogiline sobivus, bioloogiline testimine, hambaraviaparatuur, hambaravimaterjalid, kindlaksmääramine, meditsiiniaparatuur, stomatoloogia, testimine

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7405

December 2008

ICS 11.060.10; 11.100

Supersedes EN ISO 7405:1997

English Version

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008)

Art dentaire - Évaluation de la biocompatibilité des dispositifs médicaux utilisés en art dentaire (ISO 7405:2008)

Zahnheilkunde - Beurteilung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten (ISO 7405:2008)

This European Standard was approved by CEN on 5 December 2008.

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

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, 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 7405:2008: E

Foreword

This document (EN ISO 7405:2008) 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 June 2009, and conflicting national standards shall be withdrawn at the latest by June 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7405:1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7405:2008 has been approved by CEN as a EN ISO 7405:2008 without any modification.

Contents

Page

Introduction

This International Standard concerns the evaluation of the biocompatibility of medical devices used in dentistry. It is to be used in conjunction with the ISO 10993 series of standards. This International Standard contains special tests, for which ample experience exists in dentistry and which acknowledge the special needs of dentistry.

Only test methods for which the members of the committee considered there was sufficient published data have been included. In recommending test methods, the need to minimize the use of animals was given a high priority. It is essential that the decision to undertake tests involving animals be reached only after a full and careful review of the evidence indicating that a similar outcome cannot be achieved by other types of test. In order to keep the number of animals required for tests to an absolute minimum, consistent with achieving the objective indicated, it can be appropriate to conduct more than one type of test on the same animal at the same time, e.g. pulp and dentin usage test and pulp capping test. However, in accordance with ISO 10993-2 these tests are performed both in an efficient and humane way. On all occasions when animal testing is undertaken, such tests are conducted empathetically and according to standardized procedures as described for each test.

This International Standard does not explicitly describe test methods for occupationally related risks.

Annexes B and C are included to encourage the development of *in vitro* and *ex vivo* test methods which will further reduce the use of animals in the evaluation of the biocompatibility of medical devices used in dentistry.

Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

1 Scope

This International Standard specifies test methods for the evaluation of biological effects of medical devices used in dentistry. It includes testing of pharmacological agents that are an integral part of the device under test.

This International Standard does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

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

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

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

ISO 10993-10[1)], *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

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

ISO 10993-12:2007, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 14971, *Medical devices — Application of risk management to medical devices*

1) To be published.