



SLOVENSKI STANDARD
SIST EN ISO 7405:2009/A1:2013
01-november-2013

Zobozdravstvo - Ovrednotenje biokompatibilnosti medicinskih pripomočkov v zobozdravstvu - Dopolnilo A1: Pozitivna kontrola materiala (ISO 7405:2008/Amd 1:2013)

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry - Amendment 1: Positive control material (ISO 7405:2008/Amd 1:2013)

Zahnheilkunde - Beurteilung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten - ÄNDERUNG 1: Positivkontrolle (ISO 7405:2008/Amd 1:2013)

Art dentaire - Évaluation de la biocompatibilité des dispositifs médicaux utilisés en art dentaire - Amendement 1: Matériaux de contrôle positif (ISO 7405:2008/Amd 1:2013)

Ta slovenski standard je istoveten z: EN ISO 7405:2008/A1:2013

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 7405:2009/A1:2013 en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7405:2008/A1

July 2013

ICS 11.060.10; 11.100.99

English Version

**Dentistry - Evaluation of biocompatibility of medical devices
used in dentistry - Amendment 1: Positive control material (ISO
7405:2008/Amd 1:2013)**

Art dentaire - Évaluation de la biocompatibilité des
dispositifs médicaux utilisés en art dentaire - Amendement
1: Matériaux de contrôle positif (ISO 7405:2008/Amd
1:2013)

Zahnheilkunde - Beurteilung der Biokompatibilität von in der
Zahnheilkunde verwendeten Medizinprodukten -
ÄNDERUNG 1: Positivkontrolle (ISO 7405:2008/Amd
1:2013)

This amendment A1 modifies the European Standard EN ISO 7405:2008; it was approved by CEN on 15 May 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 7405:2008/A1:2013) 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 Amendment to the European Standard EN ISO 7405:2008 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

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.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

iTeh STANDARD PREVIEW Endorsement notice (standards.iteh.ai)

The text of ISO 7405:2008/Amd 1:2013 has been approved by CEN as EN ISO 7405:2008/A1:2013 without any modification.

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INTERNATIONAL
STANDARD

ISO
7405

Second edition
2008-12-15
AMENDMENT 1
2013-07-15

Dentistry —
Evaluation of biocompatibility of
medical devices used in dentistry
AMENDMENT 1: Positive control
material

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*Art dentaire — Évaluation de la biocompatibilité des dispositifs
médicaux utilisés en art dentaire*
AMENDEMENT 1: Matériaux de contrôle positif

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Reference number
ISO 7405:2008/Amd.1:2013(E)

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Published 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 7405:2008 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

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