



SLOVENSKI STANDARD SIST EN ISO 7405:2019

01-januar-2019

Nadomešča:

SIST EN ISO 7405:2009

SIST EN ISO 7405:2009/A1:2013

Zobozdravstvo - Ovrednotenje biokompatibilnosti medicinskih pripomočkov v zobozdravstvu (ISO 7405:2018, popravljena verzija 2018-12)

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2018, Corrected version 2018-12)

Zahnheilkunde - Beurteilung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten (ISO 7405:2018)

Médecine bucco-dentaire - Évaluation de la biocompatibilité des dispositifs médicaux utilisés en médecine bucco-dentaire (ISO 7405:2018)

Ta slovenski standard je istoveten z: EN ISO 7405:2018

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 7405:2019

en

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7405

November 2018

ICS 11.060.10; 11.100.99

Supersedes EN ISO 7405:2008

English Version

**Dentistry - Evaluation of biocompatibility of medical
devices used in dentistry (ISO 7405:2018, Corrected
version 2018-12)**

Médecine bucco-dentaire - Évaluation de la
biocompatibilité des dispositifs médicaux utilisés en
médecine bucco-dentaire (ISO 7405:2018)

Zahnheilkunde - Beurteilung der Biokompatibilität von
in der Zahnheilkunde verwendeten Medizinprodukten
(ISO 7405:2018)

This European Standard was approved by CEN on 17 August 2018.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 19 December 2018.

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-CENELEC 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-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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 7405:2019](https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019)

<https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019>

European foreword

This document (EN ISO 7405:2018) 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 May 2019, and conflicting national standards shall be withdrawn at the latest by May 2019.

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

This document supersedes EN ISO 7405:2008.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Endorsement notice

The text of ISO 7405:2018, Corrected version 2018-12 has been approved by CEN as EN ISO 7405:2018 without any modification.

[SIST EN ISO 7405:2019](https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019)

<https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019>

INTERNATIONAL
STANDARD

ISO
7405

Third edition
2018-10

Corrected version
2018-12

**Dentistry — Evaluation of
biocompatibility of medical devices
used in dentistry**

*Médecine bucco-dentaire — Évaluation de la biocompatibilité des
dispositifs médicaux utilisés en médecine bucco-dentaire*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 7405:2019](https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019)

<https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019>



Reference number
ISO 7405:2018(E)

© ISO 2018

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 7405:2019

<https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Categorization of medical devices	2
4.1 Categorization by nature of contact.....	2
4.1.1 General.....	2
4.1.2 Non-contact devices.....	3
4.1.3 Surface-contacting devices.....	3
4.1.4 External communicating devices.....	3
4.1.5 Implant devices used in dentistry.....	3
4.2 Categorization by duration of contact.....	3
4.2.1 General.....	3
4.2.2 Limited exposure devices.....	3
4.2.3 Prolonged exposure devices.....	3
4.2.4 Permanent contact devices.....	4
5 Biological evaluation process	4
5.1 General.....	4
5.2 Selection of tests and overall assessment.....	4
5.3 Selection of test methods.....	4
5.4 Types of test.....	5
5.4.1 General.....	5
5.4.2 Physical and chemical characterization.....	5
5.4.3 Group I.....	5
5.4.4 Group II.....	5
5.4.5 Group III.....	6
5.5 Re-evaluation of biocompatibility.....	6
6 Test procedures specific to dental materials	6
6.1 Recommendations for sample preparation.....	6
6.1.1 General.....	6
6.1.2 General recommendations for sample preparation.....	6
6.1.3 Specific recommendations for light curing materials.....	7
6.1.4 Specific recommendations for chemically setting materials.....	8
6.1.5 Positive control material.....	8
6.2 Agar diffusion test.....	8
6.2.1 Objective.....	8
6.2.2 Cell line.....	8
6.2.3 Culture medium, reagents and equipment.....	8
6.2.4 Sample preparation.....	9
6.2.5 Controls.....	9
6.2.6 Test procedure.....	9
6.2.7 Parameters of assessment.....	9
6.2.8 Assessment of results.....	10
6.2.9 Test report.....	11
6.3 Filter diffusion test.....	11
6.3.1 Objective.....	11
6.3.2 Cell line.....	11
6.3.3 Culture medium, reagents and equipment.....	11
6.3.4 Sample preparation.....	11
6.3.5 Controls.....	12
6.3.6 Test procedure.....	12

ISO 7405:2018(E)

6.3.7	Assessment of cell damage.....	12
6.3.8	Assessment of results.....	13
6.3.9	Test report.....	13
6.4	Pulp and dentine usage test.....	13
6.4.1	Objective.....	13
6.4.2	Animals and animal welfare.....	13
6.4.3	Test procedure.....	14
6.4.4	Assessment of results.....	19
6.4.5	Test report.....	19
6.5	Pulp capping test.....	19
6.5.1	Objective.....	19
6.5.2	Animals and animal welfare.....	19
6.5.3	Test procedure.....	20
6.5.4	Assessment of results.....	22
6.5.5	Test report.....	22
6.6	Endodontic usage test.....	22
6.6.1	Objective.....	22
6.6.2	Animals and animal welfare.....	22
6.6.3	Test procedure.....	22
6.6.4	Assessment of results.....	24
6.6.5	Test report.....	25
Annex A (informative) Types of test to be considered for evaluation of biocompatibility of medical devices used in dentistry.....		26
Annex B (informative) Dentine barrier cytotoxicity test.....		29
Annex C (informative) Endosseous dental implant usage test.....		37
Bibliography.....		41

SIST EN ISO 7405:2019

<https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019>

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This third edition of ISO 7405 cancels and replaces ISO 7405:2008 and ISO/TS 22911:2016 which have been technically revised. It also incorporates the Amendment ISO 7405:2008/Amd.1:2013.

The main changes compared to the previous edition are as follows:

- as crucial first step in the biological evaluation a material characterization is required before biological tests are conducted (see 5.4.2)
- modifications of contents of 'pulp and dentine usage test' and 'endodontic test'
- deletion of [Annex C](#) (Acute toxicity testing);
- addition of ISO/TS 22911 as new [Annex C](#).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 7405:2018 incorporates the following corrections.

- In [Table A.1](#), 3rd row, 3rd column for "Physical and/or chemical data", "ISO 10993-18" and "ISO/TS 10993-19" have been added.
- In [Table A.1](#), 3rd row, 5th column for "Cytotoxicity tests", "ISO 10993-5" has been added.
- In [Table A.1](#), 3rd row, 11th column for "Genotoxicity", "ISO 10993-3" has been added.

ISO 7405:2018(E)**Introduction**

This document describes 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 document 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 number and exposure of test 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 dentine 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 document does not explicitly describe test methods for occupationally related risks.

[Annex B](#) is 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. [Annex C](#) is based on and replaces ISO/TS 22911.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 7405:2019](#)

<https://standards.iteh.ai/catalog/standards/sist/cf4b08e7-2ede-4a94-8d00-8a96dd3ea14e/sist-en-iso-7405-2019>

Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

1 Scope

This document 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 document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *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, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of materials*

ISO/TS 10993-19, *Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials*

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

ISO 16443, *Dentistry — Vocabulary for dental implants systems and related procedure*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 10993-1, ISO 10993-12, ISO 16443 and the following apply.

ISO 7405:2018(E)

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

dental material

material and/or substance or combination of materials and/or substances specially formulated and prepared for use in the practice of dentistry and/or associated procedures

3.2

final product

medical device or device component that includes all manufacturing processes for the “to be marketed” device including packaging and sterilization, if applicable, and that includes processes prior to intended use, such as mixing, preconditioning and preparation

3.3

positive control material

well characterized material and/or substance that, when evaluated by a specific test method, demonstrates the suitability of the test system to yield a reproducible, appropriately positive or reactive response in the test system

3.4

negative control material

well characterized material and/or substance that, when evaluated by a specific test method, demonstrates the suitability of the test system to yield a reproducible, appropriately negative, non-reactive or minimal response in the test system

Note 1 to entry: In practice, negative controls include blanks, vehicles/solvents and *reference materials* (3.5).

3.5

reference material

material with one or more property values that are sufficiently reproducible and well established to enable use of the material or substance for the calibration of an apparatus, the assessment of a measurement method or for the assignment of values to materials

Note 1 to entry: For the purpose of this document, a reference material is any well characterized material and/or substance that, when tested by the procedure described, demonstrates the suitability of the procedure to yield a reproducible, predictable response. The response may be negative or positive.

3.6

in vitro pulp chamber

device that holds a thin slice of dentine between two chambers and allows fluid and molecules to filter or to diffuse across the “dentine barrier”

3.7

diffusion

establishment of passive movement of solutes (solubilized constituents) by means of a diffusion gradient through the “dentine barrier”

4 Categorization of medical devices

4.1 Categorization by nature of contact

4.1.1 General

For the purposes of this document, the classification of medical devices used in dentistry is derived from ISO 10993-1. If a device or material can be placed in more than one category, the more rigorous testing requirements shall apply. With multiple exposures the decision into which category a device is

placed shall take into account the potential cumulative effect, bearing in mind the period of time over which these exposures occur.

NOTE In this context the term dentistry includes the oromaxillofacial environment.

4.1.2 Non-contact devices

These devices do not contact the patient's body directly or indirectly, and are not included in ISO 10993-1.

4.1.3 Surface-contacting devices

These devices include those that contact the surface of intact or breached or otherwise compromised skin, the surface of intact or breached or otherwise compromised oral mucosa, and those that contact the external surfaces of dental hard tissue, including enamel, dentine and cementum.

NOTE In some circumstances, dentine and cementum are considered as surfaces, e.g. after gingival recession.

4.1.4 External communicating devices

These devices include dental devices that penetrate and are in contact with oral mucosa, dental hard tissues, dental pulp tissue or bone, or any combination of these, and are exposed to the oral environment.

NOTE This group also includes any kind of lining or base material to be used under a restoration.

4.1.5 Implant devices used in dentistry

These devices include dental implants and other dental devices that are partially or fully embedded in one or more of the following:

- a) soft tissue, e.g. subperiosteal implants and subdermal implants;
- b) bone, e.g. endosteal implants and bone substitutes;
- c) pulpodental system of the tooth, e.g. endodontic materials;
- d) any combination of these, e.g. transosteal implants.

4.2 Categorization by duration of contact

4.2.1 General

For the purposes of this document, medical devices used in dentistry are classified by duration of contact as described in ISO 10993-1 and listed in [4.2.2](#) to [4.2.4](#).

4.2.2 Limited exposure devices

Devices whose cumulative single or multiple use or contact is likely to be up to 24 h.

4.2.3 Prolonged exposure devices

Devices whose cumulative single, multiple or long-term use or contact is likely to exceed 24 h but not 30 d.