

STN	Stomatológia Vyhodnotenie biokompatibility zdravotníckych pomôcok používaných v stomatológii (ISO 7405: 2025)	STN EN ISO 7405 85 5345
------------	--	---

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

Obsahuje: EN ISO 7405:2025, ISO 7405:2025

Oznámením tejto normy sa ruší
STN EN ISO 7405 (85 5345) z júna 2019

141098

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2025
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii
v znení neskorších predpisov.

EUROPEAN STANDARD

EN ISO 7405

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2025

ICS 11.060.10; 11.100.99

Supersedes EN ISO 7405:2018

English Version

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2025)

Médecine bucco-dentaire - Évaluation de la biocompatibilité des dispositifs médicaux utilisés en médecine bucco-dentaire (ISO 7405:2025)

Zahnheilkunde - Bewertung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten (ISO 7405:2025)

This European Standard was approved by CEN on 21 June 2025.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye 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

EN ISO 7405:2025 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 7405:2025) 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 January 2026, and conflicting national standards shall be withdrawn at the latest by January 2026.

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 7405:2018.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 7405:2025 has been approved by CEN as EN ISO 7405:2025 without any modification.



International Standard

ISO 7405

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*

**Fourth edition
2025-06**

ISO 7405:2025(en)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

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
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

ISO 7405:2025(en)**Contents**

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Categorization of medical devices	3
4.1 Categorization by nature of contact.....	3
4.1.1 General.....	3
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.....	4
4.2.1 General.....	4
4.2.2 Limited exposure devices.....	4
4.2.3 Prolonged exposure devices.....	4
4.2.4 Long-term exposure devices.....	4
5 Biological evaluation process	4
5.1 General.....	4
5.2 Selection of tests and overall assessment.....	5
5.3 Selection of test methods.....	5
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.....	6
5.4.5 Group III.....	6
5.5 Re-evaluation of biocompatibility.....	6
6 Test procedures specific to dental materials	7
6.1 Recommendations for sample preparation.....	7
6.1.1 General.....	7
6.1.2 General recommendations for sample preparation.....	7
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 Control materials.....	9
6.2.6 Test procedure.....	9
6.2.7 Parameters of assessment.....	10
6.2.8 Assessment of results.....	11
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.....	12
6.3.4 Sample preparation.....	12
6.3.5 Control materials.....	12
6.3.6 Test procedure.....	12
6.3.7 Assessment of cell damage.....	13

ISO 7405:2025(en)

6.3.8	Assessment of results	13
6.3.9	Test report.....	14
6.4	Pulp and dentine usage test.....	14
6.4.1	Objective.....	14
6.4.2	Animals and animal welfare.....	14
6.4.3	Test procedure.....	14
6.4.4	Assessment of results	20
6.4.5	Test report.....	20
6.5	Pulp capping test.....	20
6.5.1	Objective.....	20
6.5.2	Animals and animal welfare.....	20
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.....	23
6.6.3	Test procedure.....	23
6.6.4	Assessment of results	25
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.....		28
Annex C (informative) Endosseous dental implant usage test.....		35
Annex D (informative) Antioxidant responsive element (ARE) reporter assay oxidative stress test.....		39
Annex E (informative) Margin of safety (MoS) for medical devices used in dentistry.....		48
Bibliography.....		57

ISO 7405:2025(en)**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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces ISO 7405:2018 which has been technically revised.

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

- update on normative references (e.g. replacement of ISO 6344-1 with ISO 6344-3);
- clarification on text of definitions and addition of definition for dentine barrier ([3.8](#));
- for the agar diffusion test ([6.2](#)) the criteria for assessment of decolorization zone ([Table 1](#)) and qualitative morphological/lysis index ([Table 2](#)) were harmonized with ISO 10993-5;
- addition of [Annex D](#) with an antioxidant responsive element (ARE) reporter assay cytotoxicity test.
- addition of [Annex E](#) “Margin of safety (MoS) for medical devices used in dentistry”.

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.

ISO 7405:2025(en)**Introduction**

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

Only the 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 in accordance with 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.

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 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

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 10993-5:2009, *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 skin sensitization*

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

ISO 10993-12:2021, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-17:2023, *Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents*

ISO 10993-18:2020, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

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

ISO 10993-23, *Biological evaluation of medical devices — Part 23: Tests for irritation*

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

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN