BSI Standards Publication

Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

National foreword

This British Standard is the UK implementation of EN ISO 7405:2025. It is identical to ISO 7405:2025. It supersedes BS EN ISO 7405:2018, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106, Dentistry.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by January 2026, and conflicting national standards shall be withdrawn at the latest by January 2026.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.

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.

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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.

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*