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Nadomešča:
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Zobozdravstvo - Ovrednotenje biokompatibilnosti medicinskih pripomočkov v zobozdravstvu (ISO/DIS 7405:2024)

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO/DIS 7405:2024)

Zahnheilkunde - Bewertung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten (ISO/DIS 7405:2024)

Médecine bucco-dentaire - Évaluation de la biocompatibilité des dispositifs médicaux utilisés en médecine bucco-dentaire (ISO/DIS 7405:2024)

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DRAFT International Standard

ISO/DIS 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*

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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, 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 of ISO 7405 cancels and replaces ISO 7405:2018 which have 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 by 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.

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.

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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 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 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.

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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 — Grain size analysis — Part 3: Determination of grain size distribution of microgrits P240 to P2 500*

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, *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 10993-18:2020/Amd 1:2022, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process — Amendment 1: Determination of the uncertainty factor*

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*

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

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

CIE S 017, *ILV: International Lighting Vocabulary*

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 10993-17, ISO 16443, CIE S 017 and the following apply.

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

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

3.1 dental material

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

Note 1 to entry: Material is included within substance in this definition.

[SOURCE: ISO 1942: 2020, 3.1.4.8, modified — Note 1 to entry has been added]

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

[SOURCE: ISO 10993-1:2018, 3.8, modified — processes prior to intended use has been added.]

3.3 positive control material

well characterized material 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 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 control materials include blanks, vehicles or 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 or substance that, when tested by the procedure described, demonstrates the suitability of the procedure to yield a reproducible, predictable response. The response can be negative or positive.

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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* (3.8)

3.7

diffusion

establishment of passive movement of solutes (solubilized constituents) by means of a diffusion gradient through the *dentine barrier* (3.8)

3.8

dentine barrier

barrier made out of a slice of dentine from human or animal origin

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 For the purposes of this document, 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 1 This group also includes any kind of lining or base material to be used under a restoration.

NOTE 2 This group does not include implant devices used in dentistry (4.1.5).

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) pulpodentinal system of the tooth, e.g. endodontic materials;

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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.

With multiple exposures to the device, 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 When calculating the duration of exposure for contact categorization of repeat use devices, the total exposure period in days between the first and last use of the medical device can be considered. For instance, the same device can be reused intermittently over a number of days, or replacement devices can be used over a number of days. If the treatment intervals are expected to be long relative to the elimination time of any leachable toxins from the body, this infrequent use can be considered as for a single treatment episode.

4.2.2 Limited exposure devices

Devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h.

4.2.3 Prolonged exposure devices

Devices whose cumulative sum of single, multiple or repeated duration of contact time is likely to exceed 24 h but not 30 d.

4.2.4 Long-term exposure devices

Devices whose cumulative sum of single, multiple or repeated contact time exceeds 30 d.

5 Biological evaluation process

5.1 General

Each medical device used in dentistry shall be subjected to a structured biological evaluation programme within a risk management process (see ISO 10993-1). Guidance on the implementation of this programme in ISO 14971 and ISO 10993-1 shall be used.

The biological evaluation programme shall include the review of data sets concerning the biological properties of each medical device used in dentistry. When this part of the biological evaluation programme indicates that one or more data sets are incomplete and that further testing is necessary, the tests shall be selected from the methods described in the ISO 10993 series of standards or in this document, or in both. If tests that are not included in these International Standards are selected, a statement shall be made that indicates that the tests described in these International Standards have been considered and shall include a justification for the selection of other tests.

For combination products the final product shall be evaluated in accordance with this document in conjunction with any applicable standards.

NOTE 1 In this context, combination products are dental devices of any kind that incorporate, or are intended to incorporate, as an integral part, a substance that:

- a) if used separately, would be a medicine or a biological product;
- b) is liable to affect the patient's body by an ancillary action.

An example would be a bone filling/augmentation device containing a growth factor (i.e. a biological product).

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For combination products, where the device and pharmacological components are packaged separately, it can be informative to test the device components alone.

All tests shall be conducted in accordance with recognized current/valid best laboratory/quality practices, where applicable.

NOTE 2 Examples of relevant guidance include GLP (Good Laboratory Practice) or ISO/IEC 17025.

5.2 Selection of tests and overall assessment

The selection of tests and the overall assessment of the results shall be carried out by an expert who has the appropriate chemical, physical and biological data concerning the device and who is aware of the intended conditions of use.

5.3 Selection of test methods

The selection of test methods shall be based upon consideration of

- a) the intended use of the medical device;
- b) the tissue(s) which the medical device may contact, and
- c) the duration of the contact.

If a test selected is not included in the International Standards, a justification for the choice of the methods shall be included in the test report for each device. If more than one test method in the same category is recommended by the standards, the selection of one test over the others shall be justified.

5.4 Types of test

5.4.1 General

In accordance with the categorization of the device, tests shall be considered for use as summarized in [Table A.1](#). This table indicates which types of test method shall be considered, but not that they are necessarily required to be carried out. A decision not to carry out a type of test identified in [Table A.1](#) shall be justified in the test report on each device. The types of test listed are regarded as a framework for the evaluation of the biocompatibility of medical devices used in dentistry. For most types of test, particular methods are identified, although for some devices it is recognized that alternative methods not included in the International Standards listed can be more appropriate.

5.4.2 Physical and chemical characterization

Material characterization of the medical device or component (see [Table A.1](#)) is a crucial first step in the biological evaluation. Material characterization, if performed, shall be conducted in accordance with ISO 10993-18 and ISO/TS 10993-19. For nanomaterials, see ISO/TR 10993-22.

The types of biological tests are listed in three groups.

Toxicological risk assessment of chemical constituents should be performed in accordance with ISO 10993-17 and the margin of safety (MoS) should be considered within the toxicological risk assessment. For the guidance for the margin of safety (MoS), see [Annex E](#).

5.4.3 Group I

This group comprises *in vitro* tests of cytotoxicity. General guidance for *in vitro* cytotoxicity tests is presented in ISO 10993-5 and shall be followed. Detailed test protocols for the agar or agarose diffusion and filter diffusion methods, appropriate to dental materials, are included in this document. The *in vitro* cytotoxicity methods include

- a) agar diffusion test (see [6.2](#));

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- b) filter diffusion test (see [6.3](#));
- c) direct contact or extract tests in accordance with ISO 10993-5;
- d) dentine barrier cytotoxicity test (see [Annex B](#));
- e) antioxidant responsive element (ARE) reporter assay cytotoxicity test (see [Annex D](#)).

NOTE 1 The order of listing does not indicate any preference for one method over another.

NOTE 2 This list does not indicate that all cytotoxicity tests mentioned need to be performed for each medical device under consideration.

NOTE 3 The use of the dentine barrier cytotoxicity test is encouraged and a description of the test is presented in [Annex B](#). References to this test are presented in the Bibliography.

NOTE 4 The use of ARE reporter assay cytotoxicity test is encouraged, if measurement of the oxidative stress of cells after exposure to test and control materials via metabolic activity is either applicable or justified or both.

5.4.4 Group II

This group comprises tests in accordance with the ISO 10993 series of standards and particular tests, where appropriate:

- a) acute systemic toxicity — oral application — in accordance with ISO 10993-11;
- b) acute systemic toxicity — application by inhalation — in accordance with ISO 10993-11;
- c) subacute and subchronic systemic toxicity — oral application — in accordance with ISO 10993-11;
- d) skin sensitization in accordance with ISO 10993-10;
- e) genotoxicity in accordance with ISO 10993-3;
- f) local effects after implantation in accordance with ISO 10993-6;
- g) irritation in accordance with ISO 10993-23.

NOTE 1 In order to allow use of the latest edition of the referenced document only, an undated cross-reference is possible. An indication of the appropriate clause and subclause is only possible for dated references. Therefore, the user of this document is requested to check the referenced documents for the appropriate clause numbers.

In the evaluation of materials following local implantation involving mineralized tissues in accordance with ISO 10993-6, examination of undemineralized sections, in addition to routine demineralized sections, is recommended.

NOTE 2 If appropriate, the local effects after implantation are evaluated in accordance with the endosseous dental implant usage test instead of ISO 10993-6 [see [5.4.5](#), d)].

5.4.5 Group III

This group comprises tests, specific for medical devices used in dentistry, not referred to in the ISO 10993 series of standards:

- a) pulp and dentine usage test (see [6.4](#));
- b) pulp capping test (see [6.5](#));
- c) endodontic usage test (see [6.6](#));
- d) endosseous dental implant usage test (see [Annex C](#)).

Endosseous dental implant usage test is not required, but if applicable, is recommended.