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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

FDIS stage

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Foreword

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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).

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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 ~~of ISO 7405~~ 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);~~(3.8);

— ~~—~~for the agar diffusion test ~~(6.2)~~(6.2) the criteria for assessment of decolorization zone ~~(Table 1)~~(Table 1) and qualitative morphological/lysis index ~~(Table 2)~~(Table 2) were harmonized with ISO 10993-5;

— ~~—~~addition of ~~Annex D~~Annex D with an antioxidant responsive element (ARE) reporter assay cytotoxicity test.

— ~~—~~addition of ~~Annex E~~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~~www.iso.org/members.html.

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~~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~~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 — Grain size analysis — Part 3: Determination and designation of grain size distribution of microgrits — Part 3: Microgrit sizes P240 to P2 500P5000*

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*

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 10993-18, 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~~https://www.iso.org/obp

— ~~—~~IEC Electropedia: available at ~~https://www.electropedia.org/~~https://www.electropedia.org/

3.1 ~~**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 ~~**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 — Wording from "and that includes processes prior to intended use…" has been added.]

3.3 ~~**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 ~~**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).

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.

3.6 ~~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)~~(3.8)

3.7 ~~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)

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 (see ~~4.1.5).~~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) ~~a)~~ soft tissue, e.g. subperiosteal implants and subdermal implants;

b) ~~b)~~ bone, e.g. endosteal implants and bone substitutes;

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

d) ~~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 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 days.

4.2.4 Long-term exposure devices

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

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). The implementation of this programme shall be in accordance with ISO 14971 and ISO 10993-1.