



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**



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Published in Switzerland

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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”.

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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.