
Dentistry —
Evaluation of biocompatibility of
medical devices used in dentistry
AMENDMENT 1: Positive control
material

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*Art dentaire — Évaluation de la biocompatibilité des dispositifs
médicaux utilisés en art dentaire*
AMENDEMENT 1: Matériaux de contrôle positif

[ISO 7405:2008/Amd 1:2013](https://standards.iso.org/standards/catalog/standards/sist/4cac4eca-7603-47b7-a1d3-d6178bca21c2/iso-7405-2008-amd-1-2013)

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

Amendment 1 to ISO 7405:2008 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

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Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

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Title page

Replace the French title with the following:

Médecine bucco-dentaire — Évaluation de la biocompatibilité des dispositifs médicaux utilisés en médecine bucco-dentaire

Page 7, 6.1.4

Add the following new subclause:

6.1.5 Positive control material

For both *in vitro* and *in vivo* tests, it is advisable to include a standard positive control material, which is handled and processed like the test materials (i.e. being plastic after mixing and then setting) and which is based on freely available chemicals or materials. Such a positive control material for *in vitro* testing of plastic filling materials is described in Annex B, Table B.1. The use of this specific positive control material is optional and other materials with a validated history and other well characterized positive control materials with reproducible data on toxicity can be used instead.

Page 30, Annex B, Table B.1

Add the following note in a footer row at the bottom of the table:

NOTE See Reference [31].

Page 34, Bibliography

Add the following reference:

- [31] SCHMALZ, G., HILLER, K.-A., SEIDENADER, C. and SCHWEIKL, H., *Interlaboratory testing of a new cytotoxic reference dental restorative material*. J Dent Res., **90**, Spec Issue A, 2011 (www.dentalresearch.org), Abstract # 273, <http://iadr.confex.com/iadr/2011sandiego/webprogram/schedule/Paper146565.html>.

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