
**Biological evaluation of medical devices —
Part 14:
Identification and quantification of
degradation products from ceramics**

Évaluation biologique des dispositifs médicaux —

*Partie 14: Identification et quantification des produits de dégradation des
céramiques*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 part of ISO 10993 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 10993-14 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

- *Part 1: Evaluation and testing*
- *Part 2: Animal welfare requirements*
- *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *Part 4: Selection of tests for interactions with blood*
- *Part 5: Tests for in vitro cytotoxicity*
- *Part 6: Tests for local effects after implantation*
- *Part 7: Ethylene oxide sterilization residuals*
- *Part 8: Selection and qualification of reference materials for biological tests*
- *Part 9: Framework for identification and quantification of potential degradation products*
- *Part 10: Tests for irritation and delayed-type hypersensitivity*
- *Part 11: Tests for systemic toxicity*
- *Part 12: Sample preparation and reference materials*
- *Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *Part 14: Identification and quantification of degradation products from ceramics*
- *Part 15: Identification and quantification of degradation products from metals and alloys*
- *Part 16: Toxicokinetic study design for degradation products and leachables*

- *Part 17: Establishment of allowable limits for leachable substances using health-based risk assessment*
- *Part 18: Chemical characterization of materials*

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Introduction

This part of ISO 10993 consists of two tests for the biological evaluation of medical devices: an extreme solution test and a simulation solution test. The extreme solution test is developed as a worst-case environment and the simulation test is developed as a very common environment.

Degradation products covered by this part of ISO 10993 are formed primarily by dissolution in an aqueous environment. It is recognized that additional biological factors such as enzymes and proteins can alter the rate of degradation. Degradation by such outside factors is not addressed in this part of ISO 10993.

It should be kept in mind that a ceramic device might have extraneous chemical phases and/or elements in extremely minor amounts. Whilst these components might not be named in the original specification, they can often be suspected by the relationship that the material in question has to other materials and the expected history of the material's processing.

Once identified and quantified, the chemical composition of the degradation products form the basis for risk assessment and, if appropriate, biological safety studies according to the principles of ISO 10993-1.

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