

Second edition
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**Biological evaluation of medical devices —
Part 1:
Evaluation and testing**

*Évaluation biologique des dispositifs médicaux —
Partie 1: Évaluation et essais*



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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.

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.

International Standard ISO 10993-1 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-1:1992), which has been technically revised.

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 cytotoxicity: in vitro methods*
- *Part 6: Tests for local effects after implantation*
- *Part 7: Ethylene oxide sterilization residuals*
- *Part 9: Framework for the identification and quantification of potential degradation products*
- *Part 10: Tests for irritation and sensitization*
- *Part 11: Tests for systemic toxicity*
- *Part 12: Sample preparation and reference materials*
- *Part 13: Identification and quantification of degradation products from polymers*
- *Part 14: Identification and quantification of degradation products from ceramics*

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metals and alloys

- *Part 16: Toxicokinetic study design for degradation products and leachables*

Future parts will deal with other relevant aspects of biological testing.

Annexes A, B and C of this part of ISO 10993 are for information only.

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Introduction

This part of ISO 10993 is a combination/harmonization of numerous International and national Standards and guidelines concerning the biological evaluation of medical devices. It is intended to be the overall guidance document for the selection of tests enabling evaluation of biological responses relevant to the safety of medical devices and materials.

The role of this part of ISO 10993 is to serve as a framework in which to plan such a biological evaluation which minimizes the number and exposure of test animals.

The protection of humans is the primary goal of ISO 10993.

The appropriate selection and interpretation of biological evaluation tests requires an understanding of the rationale behind such testing. An informative rationale for the use of this part of ISO 10993 is provided in annex A. Annex B contains a flow chart to aid in the systematic approach to the biological evaluation of medical devices. Annex C contains an informative bibliography.