
**Biological evaluation of medical
devices —**

Part 15:

**Identification and quantification of
degradation products from metals
and alloys**

Évaluation biologique des dispositifs médicaux —

*Partie 15: Identification et quantification des produits de dégradation
issus des métaux et alliages*

ISO 10993-15:2019

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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.

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-15:2000), which has been technically revised.

The main changes compared to the previous edition are as follows:

- a) the document now considers materials designed to degrade in the body as well as materials that are not intended to degrade;
- b) the information on test methods has been amended to consider nanomaterials and relevant material specific standards;
- c) the test solution (electrolyte) has been specified more;
- d) the sample shape has been specified more;
- e) the immersion test procedure has been expanded;
- f) the status of [Annex C](#) in the previous edition has been changed and now included as [Annex A](#).

A list of all parts in the ISO 10993 series can be found on the ISO website.

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