Second edition
2019-11

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

Reference number
ISO 10993-15:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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Foreword

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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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

One of the potential health hazards resulting from medical devices can be due to the interactions of their electrochemically induced degradation products with the biological system. Therefore, the evaluation of potential degradation products from metallic materials by methods suitable for testing the electrochemical behaviour of these materials is a necessary step in the biological performance testing of materials.

The body environment typically contains cations of sodium, potassium, calcium, and magnesium, and anions of chloride, bicarbonate, phosphate, and organic acids generally in concentrations between 2×10^{-3} mol/l and 150×10^{-3} mol/l. A range of organic molecules such as proteins, enzymes, and lipoproteins are also present, but their concentrations can vary to a great extent. Earlier studies assumed that organic molecules did not exert a significant influence on the degradation of metallic implants, but newer investigations indicate that implant–tissue interactions should be taken into account. Depending on a particular product or application, altering the pH of the testing environment may also need to be considered.

In such biological environments, metallic materials may undergo a certain degradation, and the different degradation products can interact with the biological system in different ways. Therefore, the identification and quantification of these degradation products is an important step in evaluating the biological performance of medical devices.