NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.15-2022

Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys

Issued on: December 30, 2022 **Implemented on: January 1, 2024**

Issued by: SAMR; SAC

Table of Contents

Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for

Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents.

This Document is Part 15 of GB/T (Z) 16886 Biological Evaluation of Medical Devices. GB/T (Z) 16886 has published the following parts:

--- Part 1: Evaluation and Testing within a Risk Management Process;

--- 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 9: Framework for Identification and Quantification of Potential Degradation Products;

--- Part 10: Tests for Irritation and Skin Sensitization;

--- 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 Leachable;

--- Part 17: Establishment of Allowable Limits for Leachable Substances;

--- Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process;

--- Part 19: Physic-Chemical Morphological and Topographical Characterization of Materials;

--- Part 20: Principles and Methods for Immunotoxicology Testing of Medical Devices;

--- Part 22: Guidance to Nanomaterials.

This Document replaced GB/T 16886.15-2003 Biological Evaluation of Medical Devices - Part

15: Identification and Quantification of Degradation Products from Metals and Alloys.

Compared with GB/T 16886.15-2003, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications:

a) Add the scope of application of the document, that is, the description of "this Document applies to materials that are expected to degrade in vivo and materials that are not expected to degrade" (see Clause 1 of this Edition);

b) Add information on test methods for nanomaterials and other related materials (see 4.1 of this Edition);

c) Add more test solutions (electrolytes) (see 5.2 of this Edition);

d) Add more sample shapes (see 5.3.3 of this Edition);

e) Add the specific content of the immersion test (see Clause 7 of this Edition).

This Document equivalently adopts ISO 10993-15:2019 Biological Evaluation of Medical Devices - Part 15: Identification and Quantification of Degradation Products from Metals and

Alloys.

This Document made the minimum editorial modifications as follows:

--- Add the NOTEs to Figures 1 and 2.

Please note some contents of this Document may involve patents. The issuing agency of this

Document shall not assume the responsibility to identify these patents.

This Document was proposed by National Medical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on Biological Evaluation on Medical Device of Standardization Administration of China (SAC/TC 248).

Drafting organizations of this Document: Shandong Institute of Medical Devices and Drug Packaging Inspection; and Peking University.

Chief drafting staffs of this Document: Liu Aijuan, Bo Xiaowen, Zheng Yufeng, Liu Chunyue, and Xia Dandan.

The historical editions replaced by this Document are as follows:

Biological Evaluation of Medical Devices - Part 15:

Identification and Quantification of Degradation Products

from Metals and Alloys

1 Scope

This Document specifies general requirements for the design of tests for identifying and

quantifying degradation products from final metallic medical devices or corresponding material

samples finished as ready for clinical use.

This Document applies to materials that are expected and unintended to degrade in vivo and to

degradation products that result from chemical changes in the final metallic device during in

vitro degradation tests.

This Document does not apply to the evaluation of degradation occurring by purely mechanical

processes; the methodology for producing such degradation products is described in the specific

product standard, if available. This document does not cover the biological activity of

degradation products.

NOTE 1: Due to the nature of the in vitro test, the test results approximate the in vivo behavior of the

implant or material. The described chemistry is a means to generate degradation products for further

evaluation.

NOTE 2: Pure mechanical degradation mainly produces particulate debris. Although not included in the

scope of this Document, such degradation products can cause biological reactions, and perform

biological evaluation according to the methods described in other parts of GB/T(Z) 16886.

NOTE 3: Due to the wide variety of metallic materials used in medical devices, there is no specific