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NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.9-2022

Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products

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

Issued by: SAMR; SAC

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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 9 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

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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 16886.9-2017 Biological Evaluation of Medical Devices - Part

9 Framework for Identification and Quantification of Potential Degradation Products.

Compared with GB/T 16886.9-2017, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications.

a) Change "biodegradation" to "degradation" (see Clause 1, 4.1, 4.3, 4.4, Annex B of this Edition; Clause 1, 4.1, 4.3, 4.4, Annex B of the 2017 Edition);

b) Add information on test methods for nanomaterials and related materials (see Clause 4 of

this Edition; Clause 4 of the 2017 Edition).

This Document equivalently adopts ISO 10993-9.2019 Biological Evaluation of Medical

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Devices - Part 9.Framework for Identification and Quantification of Potential Degradation Products.

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 Shandong Institute of Non-Metallic Materials.

Chief drafting staffs of this Document. Guo Lijuan, Du Fuying, Li Ying, Wu Changyan, Liu Xia, and Peng Jian.

The historical editions replaced by this Document are as follows.

--- GB/T 16886.9-2001 was first-time published in 2001; and first-time revised in 2017;

--- It is the second-time revised hereby.

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1 Scope

This Document provides general principles for the systematic evaluation of the potential and observed degradation of medical devices through the design and performance of in vitro degradation studies. Information obtained from these studies can be used in the biological evaluation described in the GB/T (Z) 16886 series.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

ISO 10993-1 Biological evaluation of medical devices - Part 1.Evaluation and testing

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within a risk management process

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1 and the following apply.

Action of a non-endogenous (foreign) material or substance passing through or being assimilated by cells and/or tissue over time.

4 Principles for Design of Degradation Studies

Careful consideration of the potential for intended or unintended degradation of a material is

essential to the evaluation of the biological safety of a device.

A degradation study plan complete with the purpose of the study shall be designed and documented to address the issues identified in 4.1.

5 Study Report

The study report shall include the following information, where relevant.

Annex A

(Normative)

Consideration of the Need for Degradation Studies

Degradation studies shall be considered if.

Annex B

(Informative)

Degradation Study Considerations

This annex contains aspects that need to be considered in the evaluation of possible degradation.

Appropriate practical studies should be considered in the case where essential information is

missing on the degradation of devices or materials and the biological effects of potential

degradation products.

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