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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 16886.12-2023

**Biological evaluation of medical devices - Part 12: Sample
preparation and reference materials**

医疗器械生物学评价 第12部分：样品制备与参照材料

(English Translation)

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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 12 of GB/T (Z) 16886 Biological Evaluation of Medical Devices. GB/T (Z) 16886 consists of 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.Physio-chemical, morphological and topographical characterization of materials;
- Part 20.Principles and methods for immunotoxicology testing of medical devices;
- Part 22.Nanomaterials guide;
- Part 23.Tests for irritation.

This Document replaced GB/T 16886.12-2017 Biological Evaluation of Medical Devices - Part

12 Sample Preparation and Reference Materials. Compared with GB/T 16886.12-2017, the

major technical changes of this Documents are as follows besides the structural adjustments

and editorial modifications.

a) Change the "Scope" to cover only the extraction of biological evaluation tests (see Clause

1 of this Edition; Clause 1 of the 2017 Edition);

b) Delete the terms and definitions of "accelerated extraction" and "simulated use extraction" (see 3.1 and 3.14 of the 2017 Edition); and change the definitions of "strict extraction", "extreme extraction", "extractables" and "leachable" (see 3.3, 3.4, 3.7 and

3.9 of this Edition; 3.4, 3.5, 3.8 and 3.10 of the 2017 Edition);

c) Change the list items of extraction conditions (see 10.3.1 of this Edition; 10.3.1 of the **2017 Edition).**

This Document equivalently adopts ISO 10993-12:2021 Biological Evaluation of Medical Devices - Part 12. Sample Preparation and Reference Materials.

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 Medical Device and Drug Packaging Inspection Institute; and Sichuan University.

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The historical editions replaced by this Standard are as follows.

--- GB/T 16886.12-2000 was first-time published in 2000; first-time revised in 2005; and second-time revised in 2017.

--- It is third-time revised hereby.

1 Scope

This Document specifies requirements and gives guidance on the procedures in the preparation

of samples and the selection of reference materials for medical device testing primarily in

biological test systems primarily in accordance with one or more parts of the ISO 10993 series.

Specifically, this document addresses the following.

2 Normative References

There are no normative references in this Document.

3 Terms and Definitions

For the purposes of this Document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses.

Substance that can be released from a medical device or material using either extraction solvents or extraction conditions, or both, that are expected to be at least as aggressive as the conditions of clinical use.

4 General Requirements

When identifying hazards and estimating risk in relation to medical devices, hazards that arise

from changes in the manufacturing process, or insufficient control of the manufacturing process,

shall be considered in the design and preparation of test samples, as described in ISO 14971.

5 Reference Materials (RMs)

Certification of a RM is a procedure that establishes the numerical or qualitative value of the

biological response of the material under the specified test conditions. This process serves to

validate the testing of the material for that particular response and results in the issuance of a

certificate.