



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

GB 4806.8-2022

**National food safety standard - Food Contact Paper and Board
Materials and Their Products**

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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 the Part 16 of GB/T 16886 Biological Evaluation of Medical Devices.
GB/T

16886 has issued 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 for Tests for Interactions with Blood;
- Part 5.Tests for Cytotoxicity. in Vitro Methods;
- 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 Leachables;

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

--- Part 18. Chemical Characterization of Materials;

--- Part 19. Physico-Chemical, Morphological and Topographical Characterization of Materials;

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

This Document replaced GB/T 16886.16-2013 Biological Evaluation of Medical Devices - Part

16 Toxicokinetic Study Design for Degradation Products and Leachables. Compared with

GB/T 16886.16-2013, the major technical changes of this Document are as follows besides the

editorial modifications.

--- Modify the definition of term "Absorption" (see 3.1 of this Edition; 3.1 of 2013 Edition);

--- Modify "Principles for design of toxicokinetic studies" (see Clause 4 of this Edition; Clause 4 of 2013 Edition);

--- Modify the "Guidance on test methods" (see Clause 5 of this Edition; Clause 5 of 2013 Edition);

--- Add information on toxicokinetic studies of nanomaterials (see A.4 of this Edition);

--- Modify the circumstances that shall be considered in toxicokinetic studies (see A.4 of

this Edition; A.4 of 2013 Edition).

This Document used translation method to equivalently adopt ISO 10993-16:2017
Biological

Evaluation of Medical Devices - Part 16. Toxicokinetic Study Design for Degradation
Products

and Leachables.

The Chinese document that has a consistent correspondence with the international
documents

normatively cited in this document is as follows.

--- GB/T 16886.1-2011 Biological Evaluation of Medical Devices - Part 1. Evaluation and
Testing within a Risk Management Process (ISO 10993-1:2009, IDT).

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 Quality Inspection Center for Medical
Device; and Shandong University.

Chief drafting staffs of this Document. Fan Chunguang, Liu Chenghu, Hou Li, Zhang Na,
Liu

Xiangdong, and Dong Xiuli.

The historical editions replaced by this Document are as follows.

--- GB/T 16886.16-2003 was first-time published in 2003; first-time revised in 2013;

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

1 Scope

This Document provides principles on designing and performing toxicokinetic studies
relevant

to medical devices. Annex A describes the considerations for inclusion of toxicokinetic
studies

in the biological evaluation of medical devices.

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 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.

Process by which a biomaterial is degraded in the physiological environment and the product(s)

eliminated and/or absorbed.

Time for the concentration of a specified substance to decrease to 50 % of its initial value in the same body fluid or tissue.

4 Principles for Design of Toxicokinetic Studies

For analytical methods, other parts of ISO 10993 shall be used as relevant. The methods shall

be fully described in the study report (see 5.1.10). Quantitative analytical methods shall be specific, sensitive and reproducible (see ISO 10993-18). Limit of detection/quantification shall

be defined and justified.

5 Guidance on Test Methods

Absorption depends on the route of administration, the physicochemical form of the test substance and the vehicle. It can be estimated from blood, serum, excreta and tissue