NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.4-2022

Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood

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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 Part is Part 4 of GB/T 16886 Biological Evaluation of Medical Devices. GB/T 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.Test 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 Materials;

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

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

This Document replaced GB/T 16886.4-2003 Biological Evaluation of Medical Devices - Part

4 Selection of Tests for Interactions with Blood. Compared with GB/T 16886.4-2003, the major

technical changes are as follows besides the structural adjustments and editorial modifications.

a) Change some terms; and add new terms and definitions (see Clause 3 of this Edition; Clause 3 of 2003 Edition);

b) Merge Tables 1 and 2 of 2003 Edition into a new Table 1 of this Edition; reorganize the test types and head of form to emphasize and include material- and mechanically-mediated hemolysis tests and in vitro and in vivo tests for assessing thrombotic risk (see Table 1 of this Edition; Tables 1 and 2 of 2003 Edition);

c) Merge Tables 3 and 4 of 2003 Edition into a new Table 2 of this Edition that briefly lists the recommended and most commonly used tests (see Table 2 of this Edition; Tables 3 and 4 of 2003 Edition);

d) Change the flow chart of the interaction test with blood (see Figure 1 of this Edition; Figure 1 of 2003 Edition);

e) Add procedures for conducting interaction tests with blood (see 6.1.15 of this Edition).

This Document equivalently adopt ISO 10993-4.2017 Biological Evaluation of Medical Devices - Part 4.Selection of Tests for Interactions with Blood.

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 of Standardization Administration of China (SAC/TC 248).

Drafting organizations of this Document. Shandong Institute of Medical Device and Pharmaceutical Packaging Inspection; Sichuan University (Sichuan Testing Center for Biomaterials and Medical Devices; and Guangdong Medical Devices Quality Surveillance and

testing Institute.

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The historical editions of this Standard and the document replaced by this Standard are as follows.

--- It is first-time published as GB/T 16886.4-2003 in 2003.

--- It is the first-time revision hereby.

1 Scope

This Document specifies general requirements for evaluating the interactions of medical devices with blood.

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, ISO 10993-

4 Abbreviated Terms

The following abbreviated terms are applicable to this Document.

Bb. Enzymatically active fragment of Factor B produced by Cleavage (by Factor D) in the activation of the Alternative Pathway.

5 Types of Devices in Contact with Blood (as Categorized in ISO 10993-1)

Implant devices are placed largely or entirely within the vascular system. Examples include but are not limited to the following.

6 Characterization of Blood Interactions