NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.18-2022

Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process

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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 18 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 16886.18-2011 Biological Evaluation of Medical Devices - Part 18.Chemical Characterization of Materials. Compared with GB/T 16886.18-2011, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications.

a) Change the scope (see Clause 1 of this Edition; Clause 1 of the 2011 Edition);

b) Add new terms and definitions (see Clause 3 of this Edition);

c) Change and add new abbreviations (see Clause 4 of this Edition; Clause 4 of the 2011 Edition);

d) Change "General Principles" to "General"; and further elaborate on the application of chemical characterization and the relationship with risk assessment (see 5.1 of this Edition; Clause 5, 6.1 of the 2011 Edition);

e) Change "Step 1 -- Qualitative information" into "Determine the structure and material composition of medical devices"; and elaborate on the collection and generation of

information required for chemical characterization (see 5.2 of this Edition; 6.2 of the

2011 Edition);

f) Change "Step 2 -- Material equivalence" into "Evaluate material/chemical equivalence with clinically established materials or medical devices"; and elaborate on material/chemical equivalence in more detail (see 5.3 of this Edition; 6.3 of the 2011 Edition);

g) Change "Step 3 -- Quantitative information", "Step 4 - Quantitative risk assessment" and "Step 5 - Estimating exposure to chemicals"; and describe in detail the progressive generation steps for quantitative chemical characterization data used for risk assessment (see 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 of this Edition; 6.3, 6.4, 6.5 of the 2011 Edition);

h) Change the general rules in "Chemical characterization parameters and methods"; and add a description about the dissolution test (see 6.1 of this Edition; 7.1 of the 2011 edition);

i) Classify and integrate the characterization parameters and test methods of polymers, metals and alloys, ceramics and natural macromolecules; and make some changes (see 6.2, 6.4 of this Edition; 7.2, 7.3, 7.4, 7.5 of the 2011 Edition);

j) Change "Report of obtained data" into "Report of chemical characterization data"; and change the information to be included in the report (see Clause 7 of this Edition; Clause

8 of the 2011 Edition);

k) Change the chemical characterization flow chart (see Figures 1~ 4 of this Edition; Figure A.1 of the 2011 Edition).

This Document equivalently adopts ISO 10993-18.2020 Biological Evaluation of Medical Devices - Part 18.Chemical Characterization of Medical Device Materials within a Risk Management Process.

This Document made the minimum editorial modification as follows.

--- Incorporated the amendments of ISO 10993-18.2020/Amd.1.2022; and the outer margins

of the terms involved are marked with vertical double lines (||).

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 Baxter Healthcare (Suzhou) Co., Ltd.

Chief drafting staffs of this Document. Shen Yong, Luo Hongyu, Bo Xiaowen, Liu Aijuan, and

Lu Qin.

The historical editions replaced by this Document are as follows.

--- GB/T 16886.18-2011 was first-time published in 2011;

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

1 Scope

This Document specifies a framework for the identification, and if necessary, quantification of

constituents of a medical device, allowing the identification of biological hazards and the

estimation and control of biological risks from material constituents, using a generally stepwise

approach to the chemical characterization.

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