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GB/T 16886.19-2022 / ISO/TS 10993-19:2020

Replacing GB/T 16886.19-2011

Biological Evaluation of Medical Devices – Part 19: Physic-Chemical, Morphological and Topographical Characterization of Materials

(ISO/TS 10993-19:2020, IDT)

医疗器械生物学评价 第 19 部分：材料物理化学、形态学和表面特性表征

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Standardization Administration of the People's Republic of China.

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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 19 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 16886.19-2011 *Biological Evaluation of Medical Devices - Part 19: Physic-Chemical, Morphological and Topographical Characterization of Materials*. Compared with GB/T 16886.19-2011, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications:

a) Add the basic principles of chemical characterization and physicochemical, morphological and topographical (PMT) in judging equivalence (see Clause 4 of this Edition; Clause 5 of the 2011 Edition);

b) Add the content of "methodological abbreviations" (see Table A.1 of this Edition; Table 1 of the 2011 Edition);

c) Add the content of "characteristic parameters and method examples"; and divide Table 2 of the 2011 Edition into two tables: one lists typical methods; and the other lists other methods (that is, less used methods) (see Table A.2 and Table A.3 of this Edition; Table 2 of the 2011 Edition).

This Document equivalently adopts ISO/TS 10993-19:2020 *Biological Evaluation of Medical Devices – Part 19: Physic-Chemical, Morphological and Topographical Characterization of Materials*. The type of document is adjusted into Chinese standard from ISO technical specification.

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 University.

Chief drafting staffs of this Document: Wan Min, Lu Wenbo, Lv Yupeng, Wang Changbin, and Liu Bing.

The historical editions replaced by this Document are as follows:

--- GB/T 16886.19-2011 was first-time published in 2011;

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

Biological Evaluation of Medical Devices – Part 19: Physic-chemical, Morphological and Topographical Characterization of Materials

1 Scope

This document provides a compilation of parameters and test methods that can be useful for the identification and evaluation of the physical, i.e., physic-chemical, morphological and topographical (PMT) properties of materials in finished medical devices. Such an assessment is limited to those properties that are relevant to biological evaluation and the medical device's intended use (clinical application and duration of use) even if such properties overlap with clinical effectiveness.

This Document is applicable to the final medical device materials.

This document does neither address the identification or quantification of degradation products nor the evaluation of the physic-chemical properties of the degraded materials, which are covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15. Chemical characterization of materials is covered by ISO 10993-18.

GB/T (Z) 16886 (all parts) is not applicable when the material or device is not in contact with the body directly or indirectly.

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

NOTE: GB/T 16886.1-2022 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, IDT)

ISO 10993-18 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process

otherwise represent the final product.

5.3 Material equivalence

As a part of material suitability assessment, a comparison of these data should be made to determine whether this material is equivalent to that utilized in a device or prototype with the same clinical exposure/use and having had the same manufacturing and sterilization processes applied, e.g., established safe and effective use of materials in a product to be used on intact skin. Annex A gives further guidance on judging material equivalency.

NOTE: Discussion on nanomaterials is presented in ISO/TR 10993-22. See also GB/T 16886.18-2022, Annex C for more on material equivalence.

Where qualitative material characterization data alone have not provided sufficient data for a material suitability assessment to be completed, quantitative material characterization data should be established, documented and subjected to assessment of suitability and risk.

5.4 Quantitative assessment

Sufficient quantitative characterization information should be obtained in order to permit an assessment of the fitness of all of the materials in a finished device for their intended purpose as part of the overall biological evaluation of the medical device. This quantitative characterization information can be usefully compared with data for materials and/or finished medical devices clinically established as being safe and effective for the intended use. The characterization information can also be usefully compared to those materials/products found not to have the required characteristics for this use. This overall evaluation is outside the scope of this document and combines information gained from many other parts of the GB/T (Z) 16886 (all parts) and utilizes ISO 14971.

6 Characterization Parameters and Methods

Clause 5 indicates the generation of qualitative and quantitative PMT characterization data for use in the suitability/risk assessment. Table 1 lists properties that are typically assessed for the characterization of materials, components, or devices. Depending on the material composition, it can be useful to evaluate for additional properties which are described in Table 2. Additional information on example methods and references used to characterize the properties are referenced in Table A.2 and Table A.3.

The characterization parameters used should be selected based on the material or finished medical device. Due to the diversity of medical devices, it is recognized that not all of the parameters identified for a material will be relevant for all/some device uses. As noted in GB/T 16886.1-2022, 6.2, the extent of characterization which should be considered is determined by the invasiveness and duration of clinical exposure in the intended use.

The analyst and material scientist in consultation with the manufacturer’s assessor of the

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