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GB/T 16886.19-2011 / ISO/TS 10993-19:2006

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

(ISO/TS 10993-19:2006, IDT)

医疗器械生物学评价 第 19 部分：

材料物理化学、形态学和表面特征性表征

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Foreword

GB/T 16886 *Biological Evaluation of Medical Devices* 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 Sensitization;

--- Part 11: Tests for Systemic Toxicity;

--- Part 12: Sample Preparation and Reference Materials;

--- Part 13: Identification and Quantification of Degradation products form 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 Substances;

--- 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 Part belongs to Part 19 of GB/T 16886.

This Part was drafted as per the rules specified in GB/T 1.1-2009.

This Part adopts the translation method to equivalently use ISO/TS 10993-19:2006 *Biological Evaluation of Medical Devices - Part 19: Physic-Chemical, Morphological and Topographical Characterization of Materials*.

The Chinese documents that have a consistent correspondence with the international documents quoted in the Normative References of this Part are 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);

GB/T 16886.18-2011 Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials (ISO 10993-18:2005, IDT).

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee for Standardization of Biological Evaluation of Medical Devices (SAC/TC 248).

Drafting organization of this Part: China Food and Drug Administration Ji'nan Quality Supervision and Inspection Center.

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

1 Scope

This Part of GB/T 16886 provides a compilation of parameters and test methods that can be useful for the identification and evaluation of the 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 Part of GB/T 16886 does not address the identification or quantification of degradation products, which are covered in Part 9, Part 13, Part 14 and Part 15 of GB/T 16886. Chemical characterization of materials is covered by GB/T 16886.18.

The GB/T 16886 series of standards is not applicable when the material or device does not contact the body directly or indirectly (see ISO 10993-1).

2 Normative References

The following documents are essential to the application of 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) are applicable to this document.

ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process

ISO 10993-18 Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 10993-18 and the following apply.

3.1 physic-chemical

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