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Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials

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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.

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.

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-

18 and the following apply.

Relating to the physical chemistry (of materials).

4 General Principles

Consideration of the PMT characterization of the materials from which a medical device is

made, like chemical characterization of materials (addressed in ISO 10993-18), is a necessary

step in assessing the biological safety and clinical effectiveness of the device.

The extent of characterization should reflect the nature and duration of the clinical exposure

and can be useful for risk assessment of the biological safety of the device.

5 Characterization Procedure

Where qualitative material characterization data alone have not provided sufficient data for a

material suitability assessment to be completed, quantitative material characterization data