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GB/T 16886.10-2017 / ISO 10993-10:2010

Replacing GB/T 16886.10-2005

Biological evaluation of medical devices -

Part 10: Tests for irritation and skin sensitization

医疗器械生物学评价

第 10 部分：刺激与皮肤致敏试验

(ISO 10993-10:2010, IDT)

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Table of Contents

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 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 leachables;
- Part 17: Establishment of allowable limits for leachable substances;
- Part 18: Chemical characterization of materials;
- Part 19: Physicochemical, morphological and topographical characterization of materials;
- Part 20: Principles and methods for immunotoxicology testing of medical devices.

This Part is Part 10 of GB/T 16886.

This Part is drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces GB/T 16886.10-2005 “Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity”. Compared with GB/T 16886.10-2005, the main technical changes are as follows:

- MODIFY the standard name;
- MODIFY the terms and definitions (Clause 3 of this Part, Clause 3 of 2005 edition);
- CANCEL the “material identification” (see 5.4 of 2005 edition);
- ADJUST the intradermal reaction test from the annex to the main text (see 6.4 of this Part, Annex B of 2005 edition);
- ADJUST the human skin irritation test from the main text to the annex (see Annex C of this Part, 6.4 of 2005 edition);
- ADD the Murine Local Lymph Node Assay (LLNA) in skin sensitization tests (see 7.2 of this Part);
- ADD the *in vitro* tests for skin irritation (see Annex D of this Part);
- ADD the method for the preparation of extracts from polymeric test materials (see Annex E of this Part).

This Part uses the translation method to be identical to ISO 10993-10:2010 “Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization”.

The documents of China that have a consistent correspondence with the international documents referenced in this Part are as follows:

GB/T 16886.2-2011 Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2006, IDT)

GB/T 16886.9-2017 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009, IDT)

GB/T 16886.12-2017 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012, IDT)

GB/T 16886.13-2017 Biological evaluation of medical devices - Part 13:

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

1 Scope

This Part of GB/T 16886 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.

This Part includes:

a) pretest considerations for irritation, including in silico and in vitro methods for dermal exposure;

b) details of in vivo (irritation and sensitization) test procedures;

c) key factors for the interpretation of the results.

Instructions are given in Annex A for the preparation of materials specifically in relation to the above tests. In Annex B several special irritation tests are described for application of medical devices in areas other than skin.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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)

ISO 10993-2 Biological evaluation of medical devices - Part 2: Animal welfare requirements

ISO 10993-9 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products

ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

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