NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.11-2021

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

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Foreword

This document is drafted in accordance with GB/T 1.1-2020 "Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents".

The document is Part 11 of GB/T 16886 "Biological evaluation of medical devices". GB/T 16886 has issued 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.Physico-chemical, morphological and topographical characterization of materials;
- Part 20.Principles and methods for immunotoxicology testing of medical devices.

This document replaces GB/T 16886.11-2011 "Biological evaluation of medical devices - Part 11.Tests for systemic toxicity". Compared with GB/T 16886.11-2011, the main technical change is as follows.

- Modify the size of groups for chronic toxicity tests (see Table 1; Table 1 of the **2011 edition).**

This document, using translation method, is identical to ISO 10993-11.2017 "Biological evaluation of medical devices - Part 11.Tests for systemic toxicity".

China's documents which have a consistent correspondence with the international documents normatively referenced in this document 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 16886.2-2011 Biological evaluation of medical devices - Part 2.Animal welfare requirements (ISO 10993-2.2006, IDT).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority of this document shall not be held responsible for identifying any or all such patent rights.

This document was proposed by National Medical Products Administration.

This document shall be under the jurisdiction of National Technical Committee 248 on Biological Evaluation of Medical Devices of Standardization Administration of China (SAC/TC 248).

Drafting organizations of this document. Shandong Quality Inspection Center for Medical Devices, National Institutes for Food and Drug Control.

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The previous releases of this document and the documents it replaces are as follows.

- It was first issued in 1997 as GB/T 16886.11-1997 and first revised in 2011;
- This is the second revision.

1 Scope

This document specifies requirements and gives guidance on procedures to be followed in the evaluation of the potential for medical device materials to cause adverse systemic reactions.

2 Normative references

The contents of the following documents, through normative references in this text, constitute indispensable provisions of this document. Among them, for dated references, only the edition corresponding to that date applies to this document. For undated references, the latest edition (including all amendments) applies 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 and the following apply.

Relationship between the dosage and the magnitude of a defined biological effect either in an individual or in a population sample.

4 General considerations

There is no absolute criterion for selecting a particular animal species for systemic toxicity testing of medical devices. However, the species used shall be scientifically justified and in line with the provisions of ISO 10993-2.