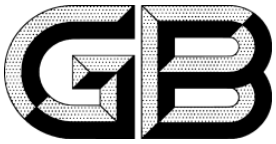

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.3-2019

Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

Issued on: June 4, 2019 **Implemented on: January 1, 2020**

Issued by: SAMR; SAC

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.Physico-chemical, morphological and topographical characterization of materials;
- Part 20.Principles and methods for immunotoxicology testing of medical devices.

This Part is Part 3 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 16886.3-2008 "Biological evaluation of medical devices - Part 3.Tests for genotoxicity carcinogenicity and reproductive toxicity".

Compared with GB/T 16886.3-2008, in addition to editorial changes, the main technical changes are as follows.

- CHANGE the test strategy by adding in vivo test and follow-up evaluation;
- ADD Annex A "Guidance on selecting an appropriate sample preparation procedure in genotoxicity testing";
- ADD further in vitro and in vivo tests, to assess the genotoxic potential of medical devices;
- ADD Annex B "Flowchart for follow-up evaluation";
- CHANGE the former Annex C to Annex E "Considerations for carcinogenicity studies performed as implantation studies" and develop specifications;
- ADD Annex F "In vitro tests for embryo toxicity".

This Part, using translation method, is identical to ISO 10993-3.2014 "Biological

evaluation of medical devices - Part 3.Tests for genotoxicity, carcinogenicity and reproductive toxicity".

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

- GB/T 16886.6-2015 Biological evaluation of medical devices - Part 6.Tests for local effects after implantation (ISO 10993-6.2007, 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 16886.18-2011 Biological evaluation of medical devices - Part 18. Chemical characterization of materials (ISO 10993-18.2005)

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 Part was proposed by National Medical Products Administration.

This Part 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 Part. Shandong Quality Inspection Center for Medical Devices, Sichuan University.

Main drafters of Part. Hou Li, Sun Xiaoxia, Liang Jie, Yuan Tun, Li Qiu.

The previous editions of the standard replaced by this Part were released as follows.

- GB/T 16886.3-1997, GB/T 16886.3-2008.

1 Scope

This Part of GB/T 16886 specifies strategies for risk estimation, selection of hazard (source) identification tests and risk management, with respect to the possibility of the following potentially irreversible biological effects arising as a result of exposure to medical devices.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 10993-12 and the following apply.

4 Requirements for test strategies

Testing may be warranted for additional states of the device such as, wear debris generated from the device or materials that cure in situ (e.g. cements, adhesives and pre-polymer mixtures) unless toxicological risk assessment determines no cause for concern from additional device/material states. For guidance on in situ curing devices see ISO 10993-12.

5 Genotoxicity tests

Unless the sample can be dissolved in a solvent compatible with the test system, appropriate extraction solvents shall be chosen on the basis of its ability to maximize extraction of the material or medical device to a level at which the concentration of genotoxic residues would be sufficient to produce a positive