NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.6-2022

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

Issued on: April 15, 2022 **Implemented on: May 1, 2023**

Issued by: SAMR; SAC

Table of Contents

Foreword... 3
Introduction... 5
1 Scope... 8
2 Normative references... 9
3 Terms and definitions... 9
4 Common provisions for implantation test methods... 10
5 Test methods, general aspects... 12
6 Test report... 20
Annex A (Normative) Test methods for implantation in subcutaneous tissue... 22
Annex B (Normative) Test method for implantation in muscle... 25
Annex C (Normative) Test method for implantation in bone... 27
Annex D (Normative) Test method for implantation in brain tissue... 30

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 6 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 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 16886.6-2015 "Biological evaluation of medical devices - Part 6.Tests for local effects after implantation". Compared with GB/T 16886.6-2015,

in addition to editorial changes, the main technical changes are as follows.

a) Add guidance on biological evaluation of absorbable medical devices (see 5.1.2, 5.3.3, 5.3.4, 6.6);

b) Add "Test method for implantation in brain tissue" (see Annex D).

This document is identical to ISO 10993-6.2016 "Biological evaluation of medical devices - Part 6.Tests for local effects after implantation".

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, Shandong University.

Main drafters of this document. Liu Jia, Sun Likui, Liu Shangming, Zhu Fuyu, Liu Zhaohua, Yu Yang.

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

- It was first issued in 1997 as GB/T 16886.6-1997 and first revised in 2015;
- This is the second revision.

1 Scope

This document specifies test methods for the assessment of the local effects after implantation of biomaterials intended for use in medical devices.

This document applies to materials that are

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, ISO 10993-2, ISO 10993-12, ISO 10993-16 and the following apply.

Action of a non-endogenous (foreign) material or substance, or its decomposition products passing through or being assimilated by cells and/or tissue step by step.

4 Common provisions for implantation test methods

For devices comprising/composed of two or more different materials, the test articles should be of similar composition or multiple implants may be needed, e.g. if a device is made of HDPE and titanium then the test article should be made of HDPE and titanium.

5 Test methods, general aspects

Each implant site shall be examined for alterations of the normal structure. This should include assessment of the regional draining lymph nodes. Use of a lens with low magnification is recommended.

The scoring system used for the histological evaluation shall take into account the extent of the area affected, either quantitatively (e.g. in micrometres) orsemiquantitatively (see Annex E).

6 Test report

The report shall include a comparative evaluation of the local effects after implantation in terms of the biological responses to test and control materials.

.....