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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.1-2022

Replacing GB/T 16886.1-2011

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

医疗器械生物学评价 第1部分：风险管理过程中的评价与试验

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Foreword

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

This document is Part 1 of GB/T 16886 "Biological evaluation of medical devices". The following parts of GB/T 16886 have been published: 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 16886.1-2011 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Apart from structural adjustments and editorial changes, the main technical changes with respect to GB/T 16886.1-2011 are as follows:

a) the scope within which, and outside which, an assessment of biological hazards is carried out was added (see Clause 1); b) some of the terms and definitions used in GB/T 16886 were added (see Clause 3); c) nanomaterials (see 3.15, 4.3, 6.1, 6.3.2, 6.3.2.13, 6.3.2.14, 6.3.2.15, B.3.1.2 and B.4.1.4) and information on the evaluation of absorbable materials (see B.4.3.3 and B.4.4.2) were added; d) the procedure for the biological evaluation of a medical device was added [see 4.1 a)]; e) content on the overall biological evaluation of a medical device was added [see 4.3 c)]; f) requirements for the biological safety evaluation over the whole life cycle of a medical device and for reusable medical devices were added (see 4.7 and 4.8);

g) the flow chart of the systematic approach to the biological evaluation of a medical device as part of risk management was changed (see Figure 1, Figure 1 of the 2011 edition); h) a requirement to carry out a biological risk evaluation of medical devices already on the market when a new version of this document is issued was added (see 4.11); i) evaluation information on non-contacting medical devices (see 5.2.1) and on transitory-contacting medical devices (see 5.3.2) was added; j) the description of medical devices contacting tissue, bone or the dentin/pulp system was changed [see 5.2.3 b), 5.2.2 b) of the 2011

edition]; k) "gap analysis and selection of the biological evaluation endpoints" was added (see 6.2);

l) the procedure to be considered when selecting the biological tests was added [see item b) 5) of 6.3.1]; m) a requirement to carry out an acute systemic toxicity test or a risk assessment was added (see 6.3.2.6); n) the principles for using animal testing to study biological endpoints were added (see 6.3.2.9); o) the circumstances in which biodegradation testing is considered were changed (see 6.3.2.13, 6.2.2.13 of the 2011 edition); p) the circumstances in which a toxicokinetic study is considered were changed (see 6.3.2.14, 6.2.2.14 of the 2011 edition).

This document is identical to ISO 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The following minimal editorial change was made: a note on the PBPK model was added to the in vivo toxicokinetic study of 6.3.2.14.

Attention is drawn to the possibility that some of the content of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying patents.

This document was proposed by the National Medical Products Administration and is under the jurisdiction of the National Technical Committee on Biological Evaluation of Medical Devices of Standardization Administration of China (SAC/TC 248).

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This document and the documents it replaces were issued as follows: first issued in 1997 as GB/T 16886.1-1997, revised a first time in 2001 and a second time in 2011; the present edition is the third revision.

1 Scope

This document specifies: the general principles governing the biological evaluation of medical devices within a risk management process; the general categorization of devices based on the nature and duration of their contact with the body; the evaluation of the existing relevant data from all sources; the identification of gaps in the available data set on the basis of a risk analysis; the identification of any further data sets necessary to analyse the biological safety of the medical device; and the assessment of the biological safety of the medical device.

This document applies to the evaluation of materials and medical devices expected to have

direct or indirect contact with: the patient's body during intended use; the user's body, if the medical device is intended for protection, such as surgical gloves, masks and the like.

This document applies to the biological evaluation of all types of medical device, active, non-active, implantable and non-implantable alike.

This document also gives guidance on the assessment of biological hazards arising from: risks caused by a medical device changing over time, as part of the overall assessment of biological safety; breakage of a medical device or of a component of a medical device that exposes body tissue to new or innovative materials.

Other parts of GB/T 16886 cover specific aspects of biological assessment and of the related testing. Mechanical performance testing is given in device-specific standards or product standards.

This document does not cover hazards related to bacteria, fungi, yeasts, viruses, transmissible spongiform encephalopathy (TSE) agents and other pathogens.

2 Normative references

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

GB/T 16886.2-2011 Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2006, IDT) · GB/T 16886.11-2021 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017, IDT) · YY/T 0316-2016 Medical devices - Application of risk management to medical devices (ISO 14971:2007, IDT) · ISO 10993-2 Biological evaluation of medical devices - Part 2: Animal welfare requirements · ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity · ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood · ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity · ISO 10993-6 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation · ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals · ISO 10993-9 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products · ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization · ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity · ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials · ISO 10993-13 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices · ISO 10993-14 Biological evaluation of medical devices - Part 14: