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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 12279.1-2024

Replacing GB 12279-2008

**Cardiovascular implants - Cardiac valve prostheses - Part 1:
General requirements**

心血管植入器械 人工心脏瓣膜 第1部分：通用要求

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is Part 1 of GB/T 12279 Cardiovascular Implantable Devices - Artificial Heart Valves. GB/T 12279 has been published.

The following two parts.

- Part 1: General requirements;
- Part 2: Surgical implantable prosthetic heart valves.

This document partially replaces the contents of GB 12279-2008 Cardiovascular Implants - Artificial Heart Valves.

Compared with the previous version, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- a) Added "Abbreviations" (see Chapter 4);
- b) Added "Basic Requirements" (see Chapter 5);
- c) Added "Device Description" (see Chapter 6);
- d) Added "Design Verification Test and Analysis/Design Confirmation" (see Chapter 7);
- e) Added the normative appendix "Packaging" (see Appendix B);
- f) Added the normative appendix "Product labeling, instructions for use and training" (see Appendix C);
- g) Added the normative appendix "Sterilization" (see Appendix D);
- h) Added the normative appendix "Guidelines for in vitro testing of pediatric devices" (see Appendix E);
- i) Added the normative appendix "Durability Test" (see Appendix I).

This document is modified to adopt ISO 5840-1:2021 "Cardiovascular implantable devices - Artificial heart valves - Part 1: General requirements".

The technical differences between this document and ISO 5840-1:2021 and their reasons are as follows.

--- ISO 5840-2 (see 7.1) has been replaced by the normative reference GB/T 12279.2 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- The normative reference GB/T 16886.1 replaces ISO 10993-1 (see 7.2.3.2) to adapt to my country's technical conditions and provide High operability;

--- ISO 11135 (see Appendix D) has been replaced by the normative reference GB 18279.1 to adapt to my country's technical conditions and improve operability.

Sex;

--- Replaced ISO 11137 (all parts) with the normative reference GB 18280 (all parts) to adapt to my country's technical conditions Improve operability;

--- Replaced ISO 11607 (all parts) with the normative reference GB/T 19633 (all parts) to adapt to my country's technical conditions Improve operability;

--- The normative reference GB/T 19974 replaces ISO 14937 (see Appendix D) to adapt to

my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 13485 (see 7.1) has been replaced by the normative reference GB/T 42061 to adapt to my country's technical conditions and improve operability.

Sex;

--- ISO 14971 (see 6.6) has been replaced by the normative reference GB/T 42062 to adapt to my country's technical conditions and improve operability.

Sex;

--- Replaced ISO 15223-1 (see C.1.1) with the normative reference YY/T 0466.1 to adapt to my country's technical conditions and improve Operability;

--- Replaced ISO 14630 (see 6.1 and 7.2.3.1) with the normative reference YY/T 0640-2016 to adapt to my country's technology Conditions, improve operability;

--- Replaced ISO 22442 (all parts) with the normative reference YY/T 0771 (all parts) Medical devices of animal origin to apply Improve operability in response to my country's technical conditions;

--- ISO 14160 (see Appendix D) has been replaced with the normative reference YY0970 to adapt to my country's technical conditions and improve operability.

Sex;

--- Replaced IEC 62366 (all parts) (see 7.2.9) with the normative reference YY/T 1474 to adapt to my country's technical conditions Improve operability;

--- The normative reference YY/T 1600 replaced ISO/T S17665-3 (see Appendix D) to adapt to my country's technical conditions and provide High operability;

--- Added reference to GB 18278.1 "Sterilization of health care products - Moist heat - Part 1: Development and confirmation of sterilization processes for medical devices" Recognition and routine control requirements (see Chapter 2);

--- Added reference to YY/T 1600 "Product families and process categories for moist heat sterilization of medical devices" (see Chapter 2);

--- Deleted "Clinical studies" (see 7.4 of ISO 5840-1:2021) and Appendix L (normative) Clinical studies of heart valve replacement devices the research endpoints and related contents should be carefully reviewed to avoid any inconsistency with the Technical Guidelines for Clinical Evaluation of Medical Devices.

The following editorial changes were made to this document.

--- The informative reference GB/T 16886.4 replaces ISO 10993-4 (see 7.2.2.2), and GB/T

19971 replaces ISO 11139 (see 3.62, 3.63), GB/T 27025 replaced ISO/IEC 17025 (see 7.1, 7.2), YY/T 0663.1 replaced ISO 25539-1 (see 3.11), YY/T 0987.1 replaced ASTM F2053, YY/T 0987.2 replaced ASTM F2052, YY/T 0987.3 replaced ASTM F2119, YY/T 0987.4 replaced ASTM F2182, and YY/T 0987.5 replaced ASTM F2213 (see 7.2.7) and YY/T 1552 replaced ISO 16429 (see F.4);

--- Merge the contents of the note to 3.12 into the definition of 3.12;

--- Move the content in the note of 3.47 to the note of 7.2.5.2;

--- Deleted A.4, A.5 in Appendix A (informative) and the echocardiography protocol section in Appendix G (informative) (see Appendix A and Appendix G).

Introduction

This document was prepared by a group of experts involved in the research and development of artificial heart valves.

The scope of this document is not covered in some areas. However, this document specifies the test types, provides test methods and/or test equipment.

This document is concerned with ensuring maximum compatibility with patients and other device users.

The risks associated with users are fully reduced, product quality is ensured, it helps doctors select artificial heart valves, and it is easy to operate during surgery.

Standardize the types of in vitro tests, preclinical in vivo evaluations, and reporting of all in vitro tests and preclinical in vivo evaluations, as well as the the process of in vitro testing and preclinical in vivo evaluation is to clarify the process required before the product is put on the market and ensure the subsequent A range of issues can be quickly identified and addressed.

Regarding in vitro tests and reports, in addition to basic material mechanical properties, physical properties, chemical properties, and biocompatibility, this document also includes Contains the most important fluid dynamics performance and durability of the system required to achieve artificial heart valves and their implantation. This document does not specify fluid dynamics it does not specify the exact test methods for mechanical properties and durability testing, but provides guidelines for test instruments.

As knowledge grows and technology improves in the field of prosthetic heart valve technology, this document may be revised, updated and/or amended.

GB/T 12279 Cardiovascular implantable devices - artificial heart valves aims to provide requirements and the test method is planned to consist of three parts.

--- Part 1: General requirements. The purpose is to provide general requirements for