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

**GB/T 12279.2-2024**

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**Cardiovascular implants - Cardiac valve prostheses - Part 2:  
Surgically implanted heart valve substitutes**

心血管植入器械 人工心脏瓣膜 第2部分：外科植入式人工心脏瓣膜

**(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 is required.

This document is Part 2 of GB/T 12279 Cardiovascular Implantable Devices - Artificial Heart Valves. GB/T 12279 has been published.

The following parts.

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

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

The requirements for use have been incorporated into GB/T 12279.1-2024. Compared with GB 12279-2008, this document has structural adjustments and editorial changes.

In addition to the above, the main technical changes are as follows.

- a) Added a chapter on "Abbreviations" (see Chapter 4);
- b) Added a chapter on "Basic Requirements" (see Chapter 5);
- c) Added a chapter on "Device Description" (see Chapter 6);
- d) "Packaging, labeling and sterilization" was changed (see 6.3.3, Chapter 10 of the 2008 edition);
- e) Added "Minimum performance requirements for devices - aortic valve" (see Table 1 in 7.2.4);
- f) Added "Minimum performance requirements for devices - mitral valve" (see Table 2 in 7.2.4);
- g) Changed "Implant durability assessment" (see 7.2.5.2, Chapter 7 of the 2008 edition);
- h) Added "Fatigue assessment of structural components of the device" (see 7.2.5.3);
- i) Added "component corrosion assessment" (see 7.2.5.4);
- j) Added "cavitation (mechanical valve)" (see 7.2.5.5);
- k) Added "tests for specific designs or processes" (see 7.2.6);
- l) Added "Device MRI compatibility" (see 7.2.7);
- m) Added "simulated use" (see 7.2.8);
- n) Added "Human factors/usability assessment" (see 7.2.9);
- o) Added "Evaluation of implant thrombosis and hemolytic potential" (see 7.2.10).

This document is modified to adopt ISO 5840-2:2021 "Cardiovascular implantable devices - Prosthetic heart valves - Part 2: Surgical implantable prosthetic heart valves" Heart Valves.

This document has the following structural adjustments compared to ISO 5840-2:2021.

- 7.4 in ISO 5840-2:2021 was deleted;
- Table F.1 corresponds to Table F.2 in ISO 5840-2:2021;
- Deleted the normative Annexes I and J in ISO 5840-2:2021.

The technical differences between this document and ISO 5840-2:2021 and their reasons are as follows.

--- Replaced ISO 5840-1:2021 with the normative reference GB/T 12279.1-2024 (see 7.2.5, 7.2.7, 7.2.8, 7.2.9 and 7.2.10) to adapt to my country's technical conditions and increase operability;

--- Replaced ISO 10993-2 (see 7.3.2) with the normative reference GB/T 16886.2 to adapt to my country's technical conditions and increase Operability;

--- ISO 14630 (see 7.3.1) has been replaced by the normative reference YY/T 0640 to adapt to my country's technical conditions and increase operability.

Sexuality;

--- Replaced ISO 16061 (see 6.3.2.3) with the normative reference YY/T 0726 to adapt to my country's technical conditions and increase the Operability;

--- Added the appendix content description (see 6.3.2.1);

--- Deleted "Clinical studies" (see 7.4 of ISO 5840-2:2021), normative Annex I "Evaluation of clinical studies based on objective performance criteria" to avoid any conflict with the "Methods for the Evaluation of Adverse Events during Clinical Studies" and the normative Appendix J "Classification of Adverse Events during Clinical Studies" Evaluation Technical Guidelines.

The following editorial changes were made to this document.

--- Replaced ISO 14971 (see A.1) with the informative reference GB/T 42062 and GB/T 39381.1-2020 ISO 12417-1:2015 (see D.2);

--- Notes are added to Table C.1 (see Appendix C);

--- Deleted the recommended reference valve information in Table F.1 of Appendix F and the description of the reference valve in F.2.2.2.

## Introduction

This document was developed for surgically implantable prosthetic heart valves and specifies the types of in vitro tests and preclinical in vivo evaluations, as well as all the purpose is to clarify the procedures required before the product is put on the market and to enable rapid Identify and manage follow-up issues.

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 artificial heart valves.

--- Part 2: Surgical implantable artificial heart valves. The purpose is to give specific requirements for surgical implantable artificial heart valves.

--- Part 3: Transcatheter implantable artificial heart valve. The purpose is to give the specific Require.

This document needs to be used in conjunction with GB/T 12279.1 and ISO 5840-3.

For some special device designs of artificial heart valves (e.g., suture-free), it is necessary to refer to this document and Relevant requirements of ISO 5840-3.

Cardiovascular implantable devices Artificial heart valves Part 2: Surgically implantable prosthetic heart valves

## 1 Scope

This document specifies the operating conditions and performance requirements for surgically implantable prosthetic heart valves and describes the risk management approach to verify/validate Methods for designing and manufacturing artificial heart valves.

Appropriate verification/confirmation tests and methods are selected through risk assessment. These test methods include Physical, chemical, biological and mechanical performance testing of artificial heart valves and their materials and components, including clinical precursors of finished artificial heart valves Internal evaluation.

This document applies to artificial heart valves that are usually implanted in the human body under extracorporeal circulation using direct visualization.

Developed and improved artificial heart valves, as well as accessories, packaging and mark.

## 2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 12279.1-2024 Cardiovascular implantable devices - Artificial heart valves - Part 1: General requirements (ISO 5840-1.

2021,MOD)

GB/T 16886.2 Biological evaluation of medical devices Part 2: Animal welfare requirements (GB/T 16886.2-2011, ISO 10993-2:2006, IDT) YY/T 0640 General requirements for passive surgical implants (YY/T 0640-2016, ISO 14630:2012, IDT) YY/T 0726 General requirements for passive surgical implants and associated devices (YY/T 0726-2020, ISO 16061:2015, MOD)