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

**GB/T 12279.3-2025**

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**Cardiovascular implants - Cardiac valve prostheses - Part 3:  
Heart valve substitutes implanted by transcatheter techniques**

心血管植入器械 人工心脏瓣膜 第3部分：经导管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.

This document is part 3 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 artificial heart valves;
- Part 3: Transcatheter implantable prosthetic heart valves.

This document is modified to adopt ISO 5840-3:2021 "Cardiovascular implantable devices - Prosthetic heart valves - Part 3: Transcatheter implantable human heart valves" Artificial Heart Valves.

This document has the following structural adjustments compared to ISO 5840-3:2021.

- Deleted 7.4 in ISO 5840-3:2021;

--- Table C.1 corresponds to Table C.2 in ISO 5840-3:2021;

--- Deleted Annex G and Annex H in ISO 5840-3:2021.

The technical differences between this document and ISO 5840-3:2021 and their reasons are as follows.

---Replace ISO 5840-1:2021 (see Chapter 5 to Chapter 7) with the normative reference GB/T 12279.1-2024.Two documents the consistency between them is modified to adapt to my country's technical conditions and improve operability;

--- Use the normative reference YY/T 0640 to replace ISO 14630 (see 7.3.1). The consistency between the two documents is equal.

The same, in order to adapt to my country's technical conditions and improve operability;

--- Use the normative reference GB/T 16886.2 to replace ISO 10993-2 (see 7.3.2). The consistency between the two documents is equal.

The same, in order to adapt to my country's technical conditions and improve operability;

--- Use the normative reference YY/T 1474 to replace IEC 62366 (see 7.3.2). The consistency between the two documents is equal.

The same, in order to adapt to my country's technical conditions and improve operability;

--- Deleted 7.4 Clinical Research, Appendix G (Normative) Classification of Adverse Events in Clinical Research and Related References.

Avoid inconsistencies with the Technical Guidelines for Clinical Evaluation of Medical Devices.

The following editorial changes were made to this document.

--- In order to coordinate with the existing standards, the statement of the standard scope has been changed;

--- GB 9706.1 replaces IEC 60601-1 (see D.1) and GB/T 12279.2 replaces ISO 5840-2 (see Introduction), GB/T 42062 replaces ISO 14971 (see B.1), YY0285.1 replaces ISO 10555-1 (see D.1), YY/T 0663.1 replaces ISO 25539-1 (see 7.2.6.1, D.1), YY/T 0694 replaces ASTM F2079 (see 7.2.6.5), YY/T 1660 replaces ASTM F3067 (see 7.2.6.6);

--- Deleted the informative reference ASTM F2081 (see 7.2.6.3 of ISO 5840-3:2021);

--- Add "The values in Tables 1 and 2 apply to new or improved human Artificial heart valves" (see 7.2.4);

--- Deleted the recommended reference valve information in Table C.1 of Appendix C and the description of the reference valve in C.2.3.2;

--- Deleted Appendix H TAVI and TMVI preoperative, perioperative and postoperative

multimodal imaging - Examples;

--- Added "Steady-state flow test" in C.2.4.2;

--- Changed the "pressure condition" in Table C.3 to "pressure difference across the closed valve";

--- Added "corresponding pressure difference across the closed valve (i.e. mean reverse pressure)" in C.2.7.

## Introduction

This document was developed for transcatheter implantable heart valve prostheses and focuses on the types of in vitro testing and preclinical in vivo evaluations, as well as all in vitro tests, reports of preclinical in vivo evaluations, device labeling and packaging. The purpose is to clarify the procedures required before the product is marketed and to Quickly identify and manage subsequent 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 12279.1-2024 and GB/T 12279.2-2024.

Cardiovascular implantable devices Artificial heart valves Part 3: Transcatheter implantable prosthetic heart valves

## 1 Scope

This document specifies the operating conditions and performance requirements for transcatheter implantable artificial heart valves (hereinafter referred to as transcatheter valves).

A method for verifying/validating the design and manufacture of transcatheter valves through risk management has been established. Appropriate verification/validation trials are selected through risk assessment.

These tests include evaluation of the physical, chemical, biological, and mechanical properties of transcatheter valves and their materials and components, as well as the