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# NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# GB 16174.2-2024

## Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers

手术植入物 有源植入式医疗器械 第2部分：心脏起搏器

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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 2 of GB 16174 "Surgical Implants - Active Implantable Medical Devices". GB 16174 has been published as follows part.

1.General requirements for safety, marking and information to be provided by the manufacturer;

2.Cardiac pacemakers. This document replaces GB 16174.2-2015 "Surgical implants - Active implantable medical devices - Part

2.Cardiac pacemakers" and Compared with GB 16174.2-2015, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

--- Changed the measurement of pulse amplitude, pulse width, pulse interval and pulse frequency (see 6.1.2,

6.1.1 of the.2015 edition);

--- Deleted the input impedance [see 6.1.4, 28.8.2d of the.2015 edition)];

--- Deleted the electrode lead conductor resistance (Rc) and sensor impedance (ZS) [see

6.2 and 28.8.3d of the.2015 edition)];

--- Changed the requirements for electrical neutrality (see 16.2,

16.2 of the.2015 edition);

--- Changed the protection of patients from thermal injury (see 17.1, Chapter 17 of the.2015 edition);

--- Changed the protection against unintended effects caused by active implantable medical devices (see 19.2,

## 1 Scope

GB 16174.2-2024 is the Chinese mandatory standard for implantable cardiac pacemakers, the pacemaker part of the active implantable medical device series and the Chinese adoption of ISO 14708-2. A pacemaker is the most demanding reliability case in medicine: it is sealed inside a person for a decade, it cannot be repaired, its failure is immediately life-threatening in a pacing-dependent patient, and it must go on working while the patient passes through airport scanners, electrosurgery, defibrillation and increasingly MRI. The standard sets the general requirements for active implantable devices as they apply to pacemakers and then the particular ones: the marking and the information supplied, the protection from unintentional biological effects and from harm caused by the device, the protection of the device from external physical and electrical forces including electromagnetic interference and defibrillation, the requirements on the power source and the elective replacement indicators, the leads and connectors, the programmer and telemetry, and the packaging, sterilisation and the tests that verify each. It is mandatory in China and takes effect on 1 September 2027.

This document specifies requirements specific to cardiac pacemakers. This document applies to active implantable medical devices for the treatment of bradyarrhythmias and devices that provide cardiac resynchronization therapy, as well as Certain non-implantable

parts and accessories of implantable medical devices. The tests specified in this document are type tests and compliance is confirmed by testing of samples. The electrical characteristics of the implantable pulse generator or electrode lead are verified by appropriate methods listed in this document or other methods. If other methods can be demonstrated to be equal to or superior in accuracy to the method specified, in case of dispute, the method specified in this document shall prevail. ISO 14708-6 covers all aspects of active implantable medical devices intended for the treatment of tachyarrhythmias. NOTE. What is often referred to as an "active implantable medical device" may in fact be a single device, a combination of multiple devices, or one or more devices in combination with one or more A combination of multiple accessories. Not all of these components are partially or fully implantable, but if non-implanted components or accessories may affect the implanted device To ensure the safety and performance of a device, requirements for non-implanted parts and accessories should be specified.



## 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 16174.1-2024 Surgical implants Active implantable medical devices Part

1.Safety, marking and information provided by the manufacturer General requirements for information ( ISO 14708-1.2014, MOD)

YY/T 0946-2014 Cardiac Defibrillator DF-1 connector assembly dimensions and test requirements for implantable cardioverter defibrillators Request ( ISO 11318.2002, MOD)

Note. There is no technical difference between the referenced content of

YY/T 0946-2014 and the referenced content of ISO 11318.2002.

YY/T 1874-2023 Electromagnetic compatibility of active implantable medical devices - implantable cardiac pacemakers, implantable cardioverter-defibrillators Electromagnetic compatibility test details for cardiac resynchronization devices and cardiac resynchronization devices ( ISO 14117.2019, IDT)

ISO 5841-3.2013 Surgical implants - Cardiac pacemakers - Part

## 3 Terms and definitions

The terms and definitions defined in GB 16174.1-2024 and the following apply to this document.