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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0989.6-2025

Replacing YY 0989.6-2016

Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

手术植入物 有源植入式医疗器械 第6部分：治疗快速性心律失常的有源植入式医疗器械（包括植入式除颤器）

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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 6 of the Active Implantable Medical Devices for Surgical Implants. The following parts

have been published.

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

2.Cardiac pacemakers;

3.Implantable neurostimulators;

5.Circulatory support devices;

6.Particular requirements for active implantable medical devices (including implantable defibrillators) for the treatment of tachyarrhythmias;

7.Particular requirements for cochlear implants and auditory brainstem implant systems. This document replaces YY 0989.6-2016 "Surgical Implants - Active Implantable Medical Devices - Part

6.Treatment of Tachyarrhythmias" Particular requirements for active implantable medical devices (including implantable defibrillators)", compared with YY 0989.6-2016, in addition to structural adjustments and In addition to the logical changes, the main technical changes are as follows:

a) The titles of Chapters 5, 20, and 28 have been changed (see Chapters 5, 20, and 28; for the.2016 edition, see Chapters 5, 20, and 28);

b) Added overall considerations (see 6.1.1);

c) The requirements for electrical neutrality have been changed (see 16.2,

16.2 of the.2016 edition);

d) The requirements for protection against thermal injury to patients have been modified (see 17.1,

1 Scope

YY 0989.6 is the particular standard for the implantable cardioverter defibrillator and the other active implants used to treat tachyarrhythmia. The prefix carries no /T, so compliance in China is mandatory. It is Part 6 of the YY 0989 series, the Chinese adoption of the international framework for active implantable medical devices, and it adds to the general requirements everything specific to a device whose job is to detect a lethal rhythm and deliver a shock: sensing, discrimination, therapy delivery, energy and the behaviour of the system when the battery approaches end of life. The 2025 edition takes effect on 1 July 2028, a three-year transition. For a manufacturer or an importer of ICDs and CRT-D systems for the Chinese market, this is the governing particular standard.

This document specifies requirements for active implantable medical devices, including implantable defibrillators, intended for the treatment of tachyarrhythmias. This document

applies to implantable cardioverter-defibrillators, implantable cardiac resynchronization therapy/defibrillators, and devices with Active implantable medical devices with a functional function and certain non-implantable components and accessories of active implantable medical devices (see Note). This document does not apply to active implantable medical devices for the treatment of bradyarrhythmias or cardiac resynchronization. GB 16174.2-2024 Such requirements are set out. NOTE

1 The tests specified in this document are type tests and compliance is confirmed by testing of samples. NOTE

2 The characteristics of the implantable pulse generator or lead are verified by the appropriate methods listed in this document or other methods. The accuracy of other methods is not guaranteed. In case of dispute, the method specified in this document shall apply. Note

3.What is often referred to as an "active implantable medical device" may actually be a single device, a combination of multiple devices, or one or more devices in combination with a Not all of these components are partially or fully implantable, but if non-implanted components or accessories may affect the implant The safety and performance of the device shall specify requirements for non-implantable components and accessories.

2 Normative references

The contents of the following documents constitute the 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)

GB 16174.2-2024 Surgical implants Active implantable medical devices Part

3 Terms and Definitions

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