ICS 11.040.40
CCS C35

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1935-2024

Requirements and test methods for safety of implantable pacemakers and cardioverter defibrillators exposed to magnetic resonance imaging

磁共振环境中植入式心脏起搏器及心律转复除颤器的安全要求和测试方法

Issued on: July 8, 2024 **Implemented on: July 20, 2025**

Issued by: National Medical Products Administration

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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. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document was prepared by the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices, Active Implants Subcommittee (SAC/TC110/ SC4) is responsible for the following. This document was drafted by: Shanghai Institute of Medical Device Inspection, National Medical Products Administration Medical Device Technical Evaluation Center, Fudan University University, Lepu Medical Electronics Instrument Co., Ltd., Chuangling Cardiac

Rhythm Management Medical Devices (Shanghai) Co., Ltd., Suzhou Wushuang Medical Equipment Co., Ltd. Limited company. The main drafters of this document are. Hu Sheng, Li Yonghua, Li Chengling, Liu Xun, Chen Ya, Yang Pengfei, Wang Jing, Wu Xiaomei, Jin Hua, Wang Yulin, Ping Lichuan. Implantable cardiac pacemakers and heart rhythm in a magnetic resonance environment Safety requirements and test methods for cardioverter defibrillators

1 Scope

YY/T 1935 addresses one of the hardest interactions in medical device safety: a cardiac implant inside an MRI scanner. It sets the requirements and the test methods for the safety of implantable pacemakers and cardioverter defibrillators exposed to magnetic resonance imaging, covering the mechanisms by which a scanner can harm a patient through their implant, from radiofrequency heating at the lead tip to gradient-induced stimulation, magnetic force and torque on the device, and disruption of its sensing and therapy. MR-conditional labelling is what lets a patient with an implant be scanned at all, and at 70,500 words this is one of the longest standards in the Chinese medical device catalogue. For a manufacturer of pacemakers, ICDs or leads seeking MR-conditional status in China, this is the governing test standard.

This document specifies 1.5T and 3.0T cylindrical devices for implantable cardiac pacemakers and cardioverter defibrillators operating with whole body coil excitation. Safety requirements for whole-body magnetic resonance equipment with round (circular or elliptical cross-section) scanning bores and the corresponding test methods are described. This document applies to implantable cardiac pacemakers and cardioverter defibrillators that meet the following conditions.

--- Systems that do not use sensing functions or are programmed not to use sensing functions during MRI scans;

---Systems that disable high voltage therapy during MRI scans;

---Device implanted in the patient's chest area. This document does not apply to non-implanted parts of active implantable medical devices. Note

1.Subcutaneous ICD systems, leadless pacemakers and implantable ECG recorders are not within the scope of this document, but the requirements and tests of this document are The test method can be used as a reference. NOTE

2 Safety requirements for magnetic resonance equipment are given in IEC 60601-2-33. Note

3.See Appendix A for a rationale for the provisions of this document.

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.

YY/T 0491-2004 Cardiac pacemakers Small cross-section connectors for implantable cardiac pacemakers (ISO 5841-3.2000, IDT)

YY/T 0946-2014 Cardiac Defibrillator DF-1 connector assembly dimensions and test requirements for implantable cardioverter defibrillators (

ISO 11318.2002,MOD) ISO /T S10974.2018 Safety assessment of magnetic resonance imaging of patients with active implantable medical devices ASTM F2052 Standard Test Method for Measurement of Magneto-Displacement Force on Medical Devices in a Magnetic Resonance Environment ment) ASTM F2182 Standard test method for measuring radiofrequency heating on or near passive implants during magnetic resonance imaging

3 Terms and definitions

The following terms and definitions apply to this document.