ICS 11.040.40
CCS C31

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0492-2026

Replacing YY/T 0492-2017

Implantable leads

植入式电极导线

Issued on: March 9, 2026 **Implemented on: March 1, 2027**

Issued by: National Medical Products Administration

Table of Contents

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. This document replaces YY/T 0492-2017 "Implantable Cardiac Pacemaker Electrode Leads". Compared with YY/T 0492-2017, except for the structure... Aside from adjustments and editorial changes, the main technical changes are as follows: --Some terminology has been changed (see Chapter 3, Chapter 3 in the.2017 edition); --Added requirements for implantable defibrillator electrode leads, implantable neurostimulator electrode leads, and extension leads (see...) 4.1.1, 4.3.3, 4.3.4, 4.4). --Electrode lead sensing impedance has been removed (see

4.3.4 in the.2017 edition). --The retention force test has been changed to connector performance (see 4.4.3,.2017 version of 4.4.3). --The requirement for accelerated aging life testing has been removed (see

4.7 in the.2017 edition). --The requirements for ethylene oxide residues have been changed (see 4.8.2,

4.9.2 in the.2017 edition). --The requirements for particulate release have been changed

(see 4.9.1,

4.10.1 in the.2017 version). --Appendix B has been amended (see Appendix B, Appendix A of the.2017 edition). Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the Active Implants Subcommittee of the National Technical Committee on Standardization of Surgical Implants and Orthopedic Devices. This document was drafted by: Tsinghua University, Shanghai Institute for Medical Device Testing, Beijing Pinch Medical Equipment Co., Ltd., and Suzhou Wuxi Medical Equipment Co., Ltd. Dual Medical Equipment Co., Ltd., Medtronic (Shanghai) Management Co., Ltd., Lepu Medical Electronics Co., Ltd., Jingyu Medical Technology (Suzhou) (State) Co., Ltd., and Hangzhou Jialiang Medical Technology Co., Ltd. The main drafters of this document are. Wang Weiming, Li Yonghua, Jiang Changqing, Chen Ya, Xu Fu, Ping Lichuan, Ge Dongdong, Zhang Botian, Zhang He, Li Peng, and Jin Hua. Deng Wei, Zhu Weiran, Cao Peng, Wen Xiongwei. The release history of this document and the document it replaces is as follows: --YY/T 0492-2004. --YY/T 0492-2017. Implantable electrode leads

1 Scope

YY/T 0492 is the standard for the wire that carries the signal, and it covers three device families at once. It specifies the requirements for implantable cardiac pacing leads, for implantable neurostimulator leads and their extensions, and for implantable cardiac defibrillator leads. The lead is the component of an active implant that moves with the body for the life of the device, and it is where insulation failure, conductor fracture and connector problems concentrate, which is why it is standardised separately from the generator it plugs into. Grouping cardiac and neurostimulation leads in one document reflects how similar their failure modes are. For a manufacturer of pacemakers, ICDs or neurostimulation systems seeking Chinese registration, this is the standard the lead testing is measured against.

This document specifies implantable cardiac pacing electrode leads, implantable neurostimulator electrode leads and extension leads, and implantable cardiac defibrillators. Requirements for electrode wires. This document applies to implantable cardiac pacing electrode leads, implantable neurostimulator electrode leads and extension leads, and implantable cardiac defibrillators. Electrode wires. Note

1.This document describes the functions of different pacemaker systems, neurostimulator systems, or defibrillator systems composed of different electrode leads, extension leads, and pulse generators. No requirements were made regarding compatibility or reliability. Note

2.The connector characteristics of implantable cardiac pacing electrode leads are specified in YY/T 0491 (IS-1) and YY/T 0972 (IS4). Implantable cardiac defibrillation electrodes. The

connector characteristics of the wires are specified by YY/T 0946 (DF-1) and YY/T 0972 (DF4). Note

3.The tests specified in this document are type tests, which are conducted on samples to evaluate the device and are not intended to be used as items for factory inspection.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. document.

GB/T 601 Preparation of Standard Titration Solutions for Chemical Reagents

GB/T 14233.1-2022 Medical infusion, transfusion and injection equipment test methods - Part

3 Terms and Definitions

The terms defined in GB 16174.1-2024, GB 16174.2-2024, YY 0989.3-2023 and YY 0989.6-2025, and the following technical terms The terms and definitions apply to this document.

3.1 Electrode lead An electrical connection device connecting the pulse generator and the target point.