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# PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# YY 0989.3-2023

## Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators

手术植入物 有源植入式医疗器械 第3部分：植入式神经刺激器

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## 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 is Part 3 of "Surgical Implants Active Implantable Medical Devices", "Surgical Implants Active Implantable Medical Devices" The following sections have been published.

1.General requirements for safety, marking and information provided by manufacturers;

3.Implantable neurostimulator;

5.Circulatory support devices;

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

7.Special requirements for cochlear implant systems. This document uses the redrafted method and is modified to adopt ISO 14708-3.2017 "Surgical Implants and Active Implantable Medical Devices - Part 3" "Implantable neurostimulator". Compared with ISO 14708-3.2017, the main technical changes and reasons for this document are as follows:

a) Regarding normative reference documents, this document has been adjusted with technical differences to adapt to my country's technical conditions and the circumstances of the adjustment. The situation is reflected in Chapter 2 "Normative Reference Documents",

and the specific adjustments are as follows: - Replace IEC 60601-1.2012 with GB 9706.1, which is modified to adopt international standards; - Replace ISO 14708-1 with GB 16174.1, which is equivalent to the international standard; - Replace IEC 61000-4-3.2006 A1.2007 A2.2010 with GB/T 17626.3, which is equivalent to the international standard; - Replace ISO 14971 with YY/T 0316, which is equivalent to the international standard; - Replace IEC 60601-1-2 with YY 9706.102, which is modified to adopt international standards.; - Added reference to GB/T 2423.43-2008 (see 23.2); - Added reference to GB/T 2423.56-2018 (see 23.2).

b) Delete the informative appendix AA in the ISO 14708-3.2017 standard. This appendix is the comparison between this document and ISO /T R14283. Correspondence table;

c) Added some updated content in ISO 14708-1.2014, because ISO 14708-3.2017 corresponds to ISO 14708-1.2014 The special requirements of ISO 14708-1.2014 are added to this special standard (see 13.1, 14.2, 16.2, 17.2,19.2,23.2,23.6,28.4,28.19,28.105). Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is sponsored by the National Surgical Implants and Orthopedic Instruments Standardization Technical Committee Active Implants Sub-Technical Committee (SAC/TC110/ SC4) Return to home.



"Surgical Implants and Active Implantable Medical Devices" contains 7 parts.

1.General requirements for safety, marking and information provided by the manufacturer. The purpose is to provide for active implantable medical devices General requirements for safety, labeling and information provided by manufacturers

2.Pacemaker. The purpose is to specify specific requirements for cardiac pacemakers

3.Implantable neurostimulator. The purpose is to specify specific requirements for implantable neurostimulators

## 1 Scope

YY 0989.3 is the mandatory Chinese standard for implantable neurostimulators, the devices that deliver electrical stimulation to the brain, spinal cord, vagus or peripheral nerves for Parkinson's disease, epilepsy, chronic pain and a widening list of other indications. It sets the particular requirements for this class within the active implantable series, covering the stimulation output and its control, the electrodes and leads, the power source and its longevity, the protection of the patient if the device malfunctions, and the information supplied to clinician and patient. Neuromodulation is among the most active areas of Chinese medical device development, with domestic deep brain stimulation systems now in clinical use. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in July 2026.

This document specifies specific requirements for implantable neurostimulators. This document applies to active implantable medical devices that perform electrical stimulation of the central nervous system or peripheral nervous system.

Note. The tests specified in this document are type tests and are performed on samples to evaluate the behavioral response of the device. These tests are not intended to be used in the manufacture of devices. Routine testing of finished products.

## 2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 2423.43-2008 Environmental testing of electrical and electronic products Part

2.Test methods vibration, impact and similar dynamics Installation of test samples (

IEC 60068-2-47.2005, IDT)

GB/T 2423.56-2018 Environmental testing Part

2.Test method Test Fh, broadband random vibration and guidelines ( IEC 60068-2-64.2008,IDT)

GB 9706.1 Medical electrical equipment Part

1.General requirements for basic safety and basic performance ( GB 9706.1-2020, IEC 60601-1.2012, MOD)

GB 16174.1 Surgical implants Active implantable medical devices Part

1.Safety, marking and communication of information provided by the manufacturer Application requirements ( GB 16174.1-2015, ISO 14708-1.2000, IDT)

GB/T 17626.3 Electromagnetic compatibility testing and measurement technology Radio frequency electromagnetic field radiation immunity test ( GB/T 17626.3- 2016, IEC 61000-4-3.2010,IDT)

YY/T 0316 Application of medical device risk management to medical devices ( YY/T 0316-2016,

ISO 14971.2007 correction version, IDT)

YY 9706.102 Medical electrical equipment Part 1-

## 3 Terms and definitions

The terms and definitions defined in GB 16174.1 (hereinafter referred to as Part 1) and the following terms and definitions apply to this document.