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

**YY/T 1996-2025**

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**Brain-computer interface medical device - Closed-loop  
implantable neurostimulator - Test methods for sensing and  
response performance**

采用脑机接口技术的医疗器械具备闭环功能的植入式神经刺激器感知与响应性能  
测试方法

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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. 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: Shanghai Institute for Medical Device Testing, Beijing Pinchi Medical Equipment Co., Ltd., and Nanhu Brain-Computer Interaction Research Institute. Research Institute, Xuanwu Hospital of Capital Medical University, Tsinghua University, Hangzhou Jialiang Medical Technology Co., Ltd., Boruikang Technology (Shanghai) Co., Ltd. Jingyu Medical Technology (Suzhou) Co., Ltd., Shenzhen Yinghe Brain Science Co., Ltd., and Changzhou Ruishenan Medical Devices Co., Ltd. The main drafters of this document are. Hu Sheng, Liu Xun, Yu Hongyi, Chen Hao, Hao Hongwei, Wang Yueming, Xiong Botao, Zhao Guoguang, Shan Yongzhi, Wang Weiming, and Yu Huiling. Cao Peng, Zeng Yan, Xu Honglai, Huang Xiaoshan, Zhu Weiran, Deng Wei, Min Xiaoyi, Xin Sheng, An Shuqing. Medical devices using brain-computer interface technology Implantable neurostimulator with closed-loop function Sensing and Response Performance Testing Methods

## 1 Scope

YY/T 1996 is one of the first standards anywhere to put a test method behind a closed-loop brain-computer interface implant. It describes how to measure the sensing and response performance of an implantable neurostimulator that uses brain-computer interface

technology and has a closed-loop function: the device reads neural signals and adjusts its own stimulation in response, and this document says how that loop is to be exercised and measured. It covers the test data requirements, the sensing performance test, the closed-loop stimulus-response test and the test of the EEG signal acquisition and processing algorithm, with an informative annex mapping test signal states onto stimulus protocol modulation. It rests on YY/T 1987 for terminology. Its two-year run-in to October 2027 is unusually long, which says how new the ground is for both manufacturers and reviewers.

This document describes an implantable neurostimulator with closed-loop functionality that utilizes brain-computer interface technology, based on the perception and response of neural signals. Performance testing methods. This document applies to implantable neurostimulators with closed-loop functionality that utilize brain-computer interface technology.

Note. For implantable neurostimulators that do not have closed-loop functionality, their ability to sense neural signals (if any) shall be tested in accordance with the relevant clauses of this document. method.

## 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.

YY/T 1987 Terminology for Medical Devices Employing Brain-Computer Interface Technology

## 3 Terms and Definitions

The terms and definitions defined in YY/T 1987 and the following terms and definitions apply to this document.

**3.1 Brain-computer interface implanted neurostimulator** Brain-computer interface technology is used to implant medical devices that provide electrical stimulation to the central nervous system.

**3.2 Algorithm performance** The efficiency and effectiveness of an algorithm when performing a specific task.

Note. This typically includes the time required for the algorithm to execute, the memory or storage space required for the algorithm to execute, and the correctness of the algorithm in solving the problem. Rate or accuracy, stability and reliability of the algorithm when

handling abnormal or noisy data, performance of the algorithm when handling datasets of different sizes, and computational efficiency. The speed of response and processing capabilities of the method in real-time applications.

**3.3 stimulation threshold** The critical value of electrical stimulation intensity that can control symptoms.

Note. Generally includes a lower threshold and an upper threshold. The lower threshold refers to the minimum electrical stimulation intensity that can control symptoms, while the upper threshold refers to the intensity that can control symptoms while stimulating related accessory pathways. The maximum safe electrical stimulation intensity that minimizes the effect.

**3.4 electrical stimulation strategy** Electrical stimulation parameters and methods are developed and applied during treatment to optimize therapeutic effects and patient comfort.