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

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Brain-computer interface medical device - Vocabulary

采用脑机接口技术的医疗器械 术语

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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. This document is published. The organization is not responsible for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the Technical Committee on Standardization of Medical Electrical Appliances (SAC/TC 10). The main drafting units of this document are. Shanghai Institute for Medical Device Testing, Nanhu Brain-Computer Interaction Research Institute, Lingang National Laboratory, and National Pharmaceutical Research Institute. Medical Device Evaluation Center of the State Food and Drug Administration, China National Institutes for Food and Drug Control, Huashan Hospital Affiliated to Fudan University, Capital Medical University Xuanwu Hospital, Beijing Tiantan Hospital affiliated to Capital Medical University, Center for Excellence in Brain Science and Intelligence Technology, Chinese Academy of Sciences, Brain-Computer Interaction and Human... The Haihe Laboratory for Machine-Machine Collaboration, Beijing Institute of Brain Science and Brain-Inspired Intelligence, Shanghai Institute of Microsystem and Information Technology, Chinese Academy of Sciences, and Tsinghua University. The main drafters of this document are. Hu Sheng, Liu Xun, Yu Hongyi, Wang Yueming, Zhou Sishu, Li Chengyu, Xie Yang, Liang Hong, Jin Ruonan, Li Shu, and Han Qianqian. Mao Ying, Chen Liang, Zhao Guoguang, Shan Yongzhi, Jia Wang, Zhou Wenjianlong, Zhao Zhengtuo, Li Xue, Ming Dong, Xu Minpeng, Luo Minmin, Zhang Lei, Tao Hu, Zhou Zhitao Hongbo. Medical device terminology using brain-computer interface technology

1 Scope

YY/T 1987 is the vocabulary the whole Chinese brain-computer interface framework is built on. It defines the terms and definitions for medical devices employing brain-computer

interface technology, abbreviated in the standards themselves to BCI medical devices. A terminology standard sounds like the least consequential document in a series until you notice that the test method standards cite it normatively: YY/T 1996, on closed-loop implantable neurostimulators, takes its terms from here, so the two are read together. It was issued in September 2025 and took effect on 1 January 2026, ahead of the test method standards that depend on it. For any company developing implanted or non-invasive BCI devices for China, this is the document that fixes what the regulator means by each term, and the place where a submission's language has to align.

This document defines the terminology and definitions for medical devices that employ brain-computer interface technology (hereinafter referred to as brain-computer interface medical devices). This document applies to brain-computer interface medical devices.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Basic Concepts

3.1.1 Brain-computer/machine interface medical devices (BCI-MD/) utilize brain-computer interface technology. BMI-MD By measuring and decoding neural signals generated by the central nervous system in real time through invasive or non-invasive methods, patients can receive external assistance or treatment. Active medical devices are those that achieve clinical effects such as improving, repairing, or replacing the function of the central nervous system through real-time two-way interaction or closed-loop feedback.

Note. Closed-loop feedback is a technique used in the field of neuromodulation. Currently, in the field of brain-computer interface medical devices, this technology is mainly applied to devices with closed-loop feedback. Medical devices such as implantable neurostimulators with specific functions.

3.1.2 Invasive brain-computer interface medical devices. BCI-MD/BMI-MD Brain-computer interface medical devices that record neural activity by piercing the skin or entering the body cavity. Note

1.For an explanation of "brain-computer interface medical devices", see Appendix A. Note

2.Invasive brain-computer interface medical devices typically employ intracranial signal technologies such as iEEG, Spike, ECoG, and sEEG. Note

3.Invasive brain-computer interface medical devices typically include semi-invasive, interventional, and implantable forms.

3.1.3 Non-invasive brain-computer interface medical devices BCI-MD/BMI-MD

Brain-computer interface medical devices that record neural activity without piercing the skin or entering body cavities.

3.2 Technical Terminology

3.2.1 event A time marker associated with a specific neural activity or external stimulus.

3.2.2 Event-related potential (ERP) Neurophysiological responses in brain electrical activity that are time-dependent on specific external or internal events.