

ICS 11.040.99  
CCS C30

**YY**

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

**YY/T 1991-2025**

---

**Artificial intelligence medical device - Computer assisted  
analysis software for stroke CT images - Algorithm  
performance test methods**

人工智能医疗器械 脑卒中CT影像辅助分析软件 算法性能测试方法

**Issued on: October 30, 2025**

**Implemented on: November 1, 2026**

---

**Issued by: National Medical Products Administration**

## Table of Contents

|                                                    |    |
|----------------------------------------------------|----|
| 1.Scope .....                                      | 1  |
| 2 Normative References .....                       | 1  |
| 3.Terms and Definitions .....                      | 1  |
| 4.Algorithm performance testing requirements ..... | 2  |
| 20 References .....                                | 24 |

## 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 unit responsible for the standardization technology of artificial intelligence medical devices. This document was drafted by: Beijing Tiantan Hospital, Capital Medical University; China National Institutes for Food and Drug Control; and the First Hospital of Jilin University. Beijing Chaoyang Hospital affiliated to Capital Medical University, Shanghai Changzheng Hospital, Center for Medical Device Evaluation of the National Medical Products Administration, Liaoning Province Medical Device Testing and Inspection Institute, Beijing Medical Device Testing Institute, Beijing University of Aeronautics and Astronautics, Tsinghua University, Shanghai United Imaging Healthcare Technology Co., Ltd., Infervision Medical Technology Co., Ltd., Shanghai Siemens Medical Devices Co., Ltd., and Hangzhou Deepwise Bolink Technology Co., Ltd. The main drafters of this document are. Wang Yongjun, Xiong Yunyun, Ye Wanxing, Li Jingli, Zhang Huimao, Yang Qi, Liu Shiyuan, Wang Jing, Meng Xiangfeng, and Li Shu. Wang Hao, Zhang Longda, Liu Di, Liu Tao, Ding Guiguang, Zhao Xiaojing, Li Na, Wang Lei, Xu Hailong.

This document serves as a methodological standard, based on different imaging modalities, targeting existing products, and focusing on auxiliary analysis of hemorrhagic stroke and ischemic stroke. For decision support tasks such as mid-brain auxiliary analysis, brain midline offset assessment, intracranial vascular assessment, and cerebral perfusion assessment, the corresponding algorithm performance indicators are evaluated. The definitions, calculation methods, and testing procedures are standardized in order to strengthen the quality evaluation of related products. Because artificial intelligence technology in this field is still developing and its application scope is constantly expanding,

new technologies should be considered in light of their suitability. New quality requirements and evaluation methods proposed after the use and risk assessment are not limited by this document. Artificial intelligence medical devices for stroke CT image assistance Analysis Software Algorithm Performance Testing Methods

## 1 Scope

YY/T 1991 is the test method China uses to decide whether an AI stroke-imaging tool actually performs. It describes how to measure the algorithm performance of software that applies artificial intelligence to the auxiliary analysis of stroke CT images, and it applies to post-processing analysis software: tools that read the scan after acquisition and support decisions on haemorrhagic and ischaemic stroke, midline shift, intracranial vessel assessment and cerebral perfusion. Software for image pre-processing or process optimisation is outside its scope. Three informative annexes carry the medical background, a worked example of a head CT test set description, and clause-by-clause methodological guidance. For a manufacturer seeking NMPA registration of an AI stroke product, this is the document the test report has to follow, and for a foreign vendor entering China it is the yardstick a domestic reviewer will apply to the algorithm evidence.

This document describes a testing method for the performance of software algorithms that use artificial intelligence technology to assist in the analysis of CT images of stroke. This document applies to auxiliary analysis software that uses artificial intelligence technology to post-process CT images of stroke. This document is not applicable to image preprocessing or process optimization software.

## 2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. 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. This document.

YY/T 1833.1 Quality Requirements and Evaluation of Artificial Intelligence Medical Devices Part

## 3 Terms and Definitions

The terms and definitions defined in YY/T 1833.1, YY/T 1833.2, and YY/T 1833.3, as well as the following terms and definitions, apply to this document.

3.1 Images obtained using computed tomography (CT) without the use of any contrast agents.

3.2 Blood samples were obtained by intravenously injecting contrast agent and performing a CT scan at the time point when the contrast agent concentration in the target blood vessel reached its peak. Enhanced imaging of the pipeline system.

3.3 Following rapid intravenous bolus injection of contrast agent, multiple consecutive CT scans of the brain region of interest were performed to obtain brain perfusion data with time-series information. Image caption.

Note. Post-processing calculations of time-density curves of brain regions of interest are performed to obtain quantified tissue blood perfusion parameters.

3.4 infarct core The area of brain tissue death caused by ischemic stroke.