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

YY/T 1907-2023

**Artificial intelligence medical device - Coronary CT image
processing software - Algorithm performance test methods**

人工智能医疗器械 冠状动脉CT影像处理软件 算法性能测试方法

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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 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 under the jurisdiction of the responsible unit for artificial intelligence medical device standardization technology. This document was drafted by: China Institute of Food and Drug Control, Shanghai Changzheng Hospital, Fuwai Hospital of the Chinese Academy of Medical Sciences, Capital Medical University Chaoyang Hospital Affiliated to the University, General Hospital of the Eastern Theater Command of the Chinese People's Liberation Army, Medical Device Technical Review Center of the State Food and Drug Administration, China Suzhou Institute of Advanced Studies of University of Science and Technology, Tsinghua University, Liaoning Provincial Medical Device Inspection and Testing Institute, Chinese People's Liberation Army General Hospital, Shanghai United Ying Intelligent Medical Technology Co., Ltd., Shanghai Siemens Medical Equipment Co., Ltd., Keya Medical Technology Co., Ltd., Shenzhen Ruixin Intelligent Medical Technology Co., Ltd., Shukun (Beijing) Network Technology Co., Ltd., Infer Medical Technology Co., Ltd., Hangzhou Shenrui Boliante Technology Co., Ltd., Philips (China) Investment Co., Ltd. The main drafters of this document. Li Jiage, Liu Shiyuan, Lu Bin, Xiao Yi, Yang Qi, Zhang Longjiang, Peng Liang, Wang Chenxi, Wang Jing, Wang Hao, Hao Ye, Meng Xiangfeng, Zhou Shaohua, Feng Jianjiang, Liu Kai, Zhang Longda, He Kunlun, Li Shu, Wu Dijia, Fei Zhenyu, Li Guang, Ma Jun, Zheng Chao, Wang Shaokang, Qiao Xin, Ge Xin, Liu Pan. Artificial intelligence medical device coronary artery CT imaging Processing software algorithm performance testing methods

1 Scope

YY/T 1907 specifies how the algorithm performance of AI-based coronary CT image processing software is tested. Where YY/T 1862 covers coronary CT software generally,

this document addresses the case where the analysis is done by a trained model, which raises questions a conventional algorithm does not: what the test set has to contain and how it is annotated, how performance is reported across patient subgroups, and how generalisation beyond the training data is demonstrated. Coronary AI is one of the most commercially advanced AI device categories in China, with several products already registered. For a developer, this is the protocol a Chinese reviewer expects the performance evidence to follow, alongside the YY/T 1833 series on AI quality requirements more broadly.

This document describes the algorithm performance testing method of coronary CT image processing software using artificial intelligence technology. This document applies to software products that use artificial intelligence technology to post-process coronary CT images. This document is not suitable for image pre-processing and process optimization. CCTA) and CT plain imaging.

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.

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, YY/T 1833.3 and the following apply to this document.

3.1 coronary centerline coronary centerline A curve formed along the axis of the blood vessel and connecting the lumen center points on each cross-sectional image of the coronary artery. The starting point of the curve is the crown The opening of the coronary artery, the end point is the clearly identifiable farthest end of each coronary artery.

Note. The coronary artery centerline is generally presented on curved images.

3.2 Fractional flow reserve calculated from coronary CT vascular images.

Note. Appendix A provides additional explanation of fractional flow reserve.

3.3 A quantitative index to calculate the degree of coronary artery calcification, usually using ECG gating before coronary CT angiography. CT plain scan (axial scan), combined with mathematical formulas to quantify coronary artery calcification. Note

1. Currently commonly used calculation methods include Agatston integral, volume integral

and mass integral. Note

2. Agatston score is a commonly used indicator of coronary artery calcium score. Appendix B provides a supplementary explanation of its calculation method. Note

3. Coronary artery calcification is characterized based on the lesion size exceeding a certain area or volume threshold and the density exceeding the prescribed CT value threshold. Different calculation methods are not all the same, the guide recommends using Agatston points.