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

**YY/T 1862-2023**

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**Particular specification of coronary CT image processing  
software**

冠状动脉CT影像处理软件专用技术条件

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## Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1. Structure and Drafting Rules for Standardization Documents" drafting. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is sponsored by the Medical X-ray Equipment and Appliances Sub-Technical Committee of the National Standardization Technical Committee of Medical Electrical Appliances (SAC/TC10/SC1) Focus on. This document was drafted by: Liaoning Medical Device Inspection and Testing Institute, Shanghai Siemens Medical Devices Co., Ltd., National Drug Administration Bureau Medical Device Technology Review Center, Shukun (Beijing) Network Technology Co., Ltd., Hangwei General Electric Medical Systems Co., Ltd., Feili Pu Medical (Suzhou) Co., Ltd., China Academy of Information and Communications Technology, Keya Medical Technology Co., Ltd., Shanghai Xingmai Information Technology Co., Ltd. Division, Shanghai United Imaging Intelligent Medical Technology Co., Ltd. The main drafters of this document. Zhang Longda, Sun Zhiyong, Tian Yi, Fei Zhenyu, Zheng Chen, Zheng Chao, Wei Dong, Wang Huaizhi, Min Dong, Cao Kunlin, Fang Que, Zhan Yiqiang. Special technical requirements for coronary artery CT image processing software

## 1 Scope

YY/T 1862 is the Chinese specification for coronary CT image processing software, the applications that reconstruct, straighten and analyse the coronary arteries from a CT angiogram and quantify stenosis, plaque and calcium. It sets the particular technical requirements such software has to meet and the methods by which they are demonstrated, covering the accuracy of the measurements it produces, the reproducibility of its segmentation, the handling of image data and the information presented to the reporting clinician. These measurements drive decisions about catheterisation and stenting, so a systematic error in the software becomes a systematic error in patient management. Software is regulated as a medical device in China in its own right. For a developer, this is the product-specific text a Chinese registration is judged against.

This document specifies the requirements and inspection methods for coronary artery CT image processing software products. This document is applicable to coronary artery CT image processing software, and X-ray computed tomography equipment and image processing software equipped with such software. Post-processing workstation.

## 2 Normative references

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

GB 9706.244 Medical Electrical Equipment Part 2-

44.Basic Safety and Essential Performance of X-ray Computed Tomography Equipment special requirements

GB/T 25000.10 System and software engineering System and software quality requirements and evaluation (SQuaRE) Part

## 3 Terms and Definitions

The following terms and definitions defined in GB 9706.244, GB/T 25000.10 and GB/T 25000.51 apply to this document.

3.1 Software for post-processing such as reconstruction, visualization, segmentation, measurement, and calculation of coronary CT images. score, CACS), etc. Note

2.See A.2.1 in Appendix A.

3.2 After intravenous injection of contrast agent, the coronary artery images obtained by collecting data from CT scans and reconstructing them through computer processing can

be used for Observe whether the anatomical structure of the heart and blood vessels is abnormal, whether there is plaque formation on the blood vessel wall, understand the degree of vascular stenosis, and evaluate coronary artery revascularization Vascular conditions before and after surgery or before and after drug treatment.

3.3 Accompanying document accompanying document The contents of the documentation accompanying the software contain information for the responsible party or operator.

3.4 operator operator The person who operates the software.

## **10 System and software Software Quality Model**

GB/T 25000.51 System and software engineering System and software quality requirements and evaluation (SQuaRE) Part

51.Ready to use Quality requirements and testing rules for software products (RUSP)

YY/T 1708.1-2020 Basic requirements for connectivity compliance of medical diagnostic X-ray imaging equipment Part