

ICS 11.040.70
CCS C40

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

YY/T 1895-2023

Intravascular optical coherence tomograph

血管内光学相干断层扫描成像设备

Issued on: September 5, 2023

Implemented on: September 15, 2024

Issued by: National Medical Products Administration

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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 sponsored by the Medical Optics and Instruments Sub-Technical Committee of the National Technical Committee on Optics and Photonics Standardization (SAC/TC103/SC1) Return to home. This document was drafted by: Zhejiang Medical Device Inspection Institute, Medical Device Technical Review Center of the State Food and Drug Administration, Suzhou MicroPort Argus Medical Technology Co., Ltd., Shenzhen Zhongke Weiguang Medical Device Technology Co., Ltd., Nanjing Wolfman Medical Technology Co., Ltd. Department, China Institute of Metrology, Jiangsu Medical Device Inspection Institute. The main drafters of this document. Wang Jingtao, Chen Min, Peng Jianhua, Wang Zhengyi, Li Jianan, Tao Kuiyuan, Hu Zhixiong, Zhang Lintao, Cao Yihui, Kuang Hao, Li Ning, Hu Yiping, Huang Tao, Ge Qun. Intravascular optical coherence tomography imaging device

1 Scope

YY/T 1895 covers intravascular optical coherence tomography systems, the catheter-based imaging that produces micron-resolution cross-sections of a coronary artery from inside it. OCT resolves the things angiography cannot: whether a stent is fully apposed to the wall, whether a plaque cap is thin enough to rupture, whether a dissection needs treating. This document sets the requirements such a system has to meet and the test methods that verify them, covering resolution, penetration depth, the pullback and its geometric accuracy, the catheter and the image processing. Intracoronary imaging is expanding quickly in

Chinese cardiology as stent optimisation becomes routine. For a manufacturer, this is the product-specific text a Chinese registration is judged against.

This document specifies the requirements, test methods, accompanying documentation and markings for intravascular optical coherence tomography imaging equipment. This document applies to instruments and accessories for tomographic imaging of coronary arteries using optical coherence tomography.

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.

GB 7247.1 Safety of laser products Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 OCT An optical interferometry technology used to obtain tomographic images of target objects, using a partially coherent narrow scanning beam to determine the internal reflection of the object. The relative depth of the surface.

3.2 Intravascular OCT device Equipment for scanning, processing and displaying OCT images of coronary arteries, including intravascular OCT host computer (including catheter connection controller) and intravascular imaging catheters.

3.3 Used in conjunction with the catheter connection controller on the intravascular OCT host, inserted into the cardiovascular system for scanning and imaging of coronary arteries of tubular instruments.

3.4 sensitivity The ratio of the optical power output by the conduit connected to the controller to the minimum detectable optical power reflected from the sample to the device.