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

YY/T 1959-2025

**Particular specifications for digital intraoral X-ray imaging
system**

口腔内数字化X射线成像系统专用技术条件

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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. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document was prepared by the Subcommittee on Standardization of Medical X-ray Equipment and Instruments of the National Technical Committee for Standardization of Medical Electrical Appliances (SAC/TC10/SC1) is under its jurisdiction. This document was drafted by: Shenzhen Zhenguan Dexin Technology Co., Ltd., and the Yangtze River Delta Medical Device Technical Review and Inspection Center of the National Medical Products Administration. Branch Center, Guangdong Provincial Drug Administration Evaluation and Certification Center, Liaoning Provincial Medical Device Testing and Inspection Institute, West China Hospital of Stomatology, Sichuan University Shanghai Yirui Optoelectronic Technology Co., Ltd., Guangdong Provincial Drug Administration Affairs Center, and Shanghai Bornden Technology Co., Ltd. The main drafters of this document are. Wu Qiu, Li Fei, Chen Zhuo, Xiao Weiwei, You Meng, Chen Yu'en, Zhang Nan, Qu Hongyan, Cao Peiyan, He Shanshan, and Peng Mengsi. Dedicated intraoral digital X-ray imaging system Technical conditions

1 Scope

YY/T 1959 is the particular specification for the digital intraoral X-ray imaging system, the sensor and software that replaced dental film. It sets the terminology and definitions for intraoral digital imaging systems, specifies their classification and composition and the requirements, and describes the corresponding test methods. Intraoral systems are judged on spatial resolution, contrast and dose at the small field sizes dentistry works in, which is why they get a particular standard rather than being covered by the general dental

radiography requirements. For a manufacturer or an importer of intraoral sensors and imaging systems seeking Chinese registration, this is the standard the type test is run against, on top of the general medical electrical safety requirements.

This document defines the terminology and definitions of intraoral digital X-ray imaging systems (hereinafter referred to as imaging systems), and specifies their classification and grouping. The requirements and corresponding experimental methods are described. This document applies to imaging systems that use digital X-ray detectors with single-exposure imaging capabilities. This document does not apply to.

---Intraoral imaging using film or light-excited phosphorescent imaging plates as X-ray receivers;

---Extraoral X-ray imaging system.

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.

GB 9706.1 Medical electrical equipment - Part

3 Terms and Definitions

The terms and definitions defined in GB 9706.1, GB 9706.265, GB/T 10149, and YY 9706.102, as well as the following terms and definitions, apply to this document.

3.1 Digital intraoral X-ray imaging system It typically consists of an image receiver that uses a digital X-ray detector as the intraoral X-ray imaging system and system software, which transmits X-rays through the dental arch. After the X-rays are converted into digital signals, they are transmitted to the image acquisition and control software via wired data transmission cables or wireless data transmission modules. Generate digital images.

Note. The system software supports image display, image processing, and image storage functions.

3.2 Digital X-ray detector After spatial sampling of X-rays using a matrix pixel structure, the X-ray photon signal is converted into digital electronic form. The signal converter for image information.

3.3 Effective imaging area The maximum effective area imaged by the detector.