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

YY 0845-2011

**Laser therapeutic equipment - Diode laser equipment for
photodynamic therapy**

激光治疗设备 半导体激光光动力治疗机

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard GB 9706.1 "Medical Electrical Equipment Part 1. General requirements for safety", GB 9706.19 "Medical Electrical Equipment Part 2. Particular requirements for the safety of endoscopic equipment ", GB 9706.20" Medical electrical equipment Part II. diagnostic and therapeutic laser equipment safety Full-specific requirements "and GB 7247.1" Safety of laser products - Part 1. Equipment Classification, Requirements and User's Guide. " Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents. This standard was proposed by the State Food and Drug Administration. This standard by the national medical and optical instruments Standardization Technical Committee (SAC/TC103/SC1) centralized. This standard by the State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center, Zhejiang Medical Device Testing, Shenzhen City Leimai Technology Co., Ltd. is responsible for drafting. The main drafters of this standard. Yeyue Shun, Han Jian City, Du Yi, Du Kun. Laser therapy equipment The semiconductor laser photodynamic therapy machine

1 Scope

YY 0845 is the mandatory Chinese standard for diode laser equipment used in photodynamic therapy, where a photosensitising drug is given, allowed to concentrate in the target tissue, and then activated by light of a matched wavelength. The whole treatment depends on the match: the laser has to emit at the absorption peak of the photosensitiser and deliver a defined light dose, or the drug is not activated and the patient carries the photosensitivity without the benefit. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering the output wavelength and power and their accuracy, the delivery system, the dose timing and the interlocks. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the terms and definitions of the semiconductor laser photodynamic therapy machine, the product composition, the basic parameters, technical requirements, test methods and Inspection rules and other requirements. This standard applies to the

semiconductor laser photodynamic therapy machine (hereinafter referred to as the treatment machine), the treatment machine uses a specific wavelength of laser and light-sensitive Agent photochemical effect, for clinical units photodynamic therapy.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 191 Packaging - Pictorial signs

GB 7247.1 Safety of laser products - Part 1. Equipment Classification, Requirements and User's Guide

GB 9706.1 Medical Electrical Equipment Part 1. General requirements for safety

GB 9706.19-2000 Medical electrical equipment - Part 2. Safety of endoscopic equipment

GB 9706.20 Medical electrical equipment - Part 2. diagnostic and therapeutic laser equipment requirements for the safety

GB/T 14710-2009 medical electrical environmental requirements and test methods

GB/T 17736-1999 laser safety goggles main parameters of the test method

YY/T 0758-2009 General Requirements for treatment with the laser fiber

YY 91057-1999 medical foot switch General technical conditions Test Method

ISO 11146 (all parts) and laser-related equipment laser beam widths, divergence angles and beam propagation ratios (Lasers and laser-related equipment-Test methods for laser beam widths, divergence angles and beam propagation ratios)

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Photodynamic therapy photodynamic therapy With the help of the photosensitizer, the participation of oxygen molecules in the light-induced chemical reaction by the light irradiation sensitization caused by this chemical reaction It should go to destroy diseased tissue for therapeutic purposes.

3.2 Wavelength spectrum width spectral bandwidth Spectral power (or energy) for half the peak wavelength interval corresponding to the maximum premises.

3.3 Therapeutic laser fiber therapeutic laser fiber In the optical fiber laser transmission medium, through the use of light treatment products.