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

YY 0846-2011

Laser therapeutic equipment - Ho: YAG laser equipment

激光治疗设备 掺钛钇铝石榴石激光治疗机

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Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions

Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. The standard safety requirements for full implementation of GB 9706.1-2007 "Medical Electrical Equipment Part 1. General requirements for safety" GB 9706.20-2000 "Medical electrical equipment - Part 2. diagnostic and therapeutic laser equipment for the safety requirements" and GB 7247.1- 2001 "Safety of laser products - Part 1. Equipment classification, requirements and user guide" requirements. GB/T 14710-2009 "medical electrical environmental requirements and test methods" of the standard. 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 was drafted. State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center, Zhejiang Medical Devices Unit The inspection. The main drafters of this standard. Qi Weiming, Yezhong Chen, Du Kun, Huang Dan. Laser therapy equipment Holmium-doped yttrium aluminum garnet laser treatment

1 Scope

YY 0846 is the mandatory Chinese standard for holmium YAG laser therapy equipment. The holmium wavelength is absorbed by water within a fraction of a millimetre, which makes it the standard tool for fragmenting urinary stones and for endoscopic soft tissue work, delivered through a flexible fibre that can be passed down a ureteroscope. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering the output energy and pulse characteristics and their accuracy, the fibre delivery system and its integrity, the aiming beam, and the interlocks and eye protection. Holmium laser lithotripsy is high-volume urology in China. Being a YY standard without the /T suffix, compliance is compulsory in China.

YY/T 0758 General Requirements for treatment with the laser fiber Medical Foot beginning

YY 91057-1999 General technical conditions

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

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety

GB 9706.19 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 medical electrical environment requirements and test methods

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

ISO 11146-1:2005 Test methods for laser and laser-related equipment laser beam widths, divergence angles and beam propagation than the first Part 1. no astigmatism and simple astigmatic beams (Lasers and laser-related equipment-Test methods for laser beam widths, divergence angles and beam propagation ratios-Part 1. Stigmatic and simple astigmatic beams)

ISO 11146-2:2005 Test methods for laser and laser-related equipment laser beam widths, divergence angles and beam propagation than the first Part 2. Generalized astigmatic beam (Lasers and laser-related equipment-Test methods for laser beam widths, divergence angles and beam propagation ratios-Part 2. General astigmatic beams) ISO / T

R11146-3:2004 Test methods for laser and laser-related equipment laser beam widths, divergence angles and beam propagation ratios Part 3. Intrinsic and geometrical laser beam classification, transmission and detailed test methods

(Lasers and laser-related equipment- Test methods for laser beam widths, divergence angles and beam propagation ratios-Part 3. Intrinsic and geometrical laser beam classification, propagation and details of test methods)

3 Terms and Definitions

The following terms and definitions apply to this document.