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

YY 1300-2016

**Therapeutic laser equipment - Pulsed Nd: YAG laser equipment
for therapy**

激光治疗设备 脉冲掺钕钇铝石榴石激光治疗机

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Table of Contents

- 1 Scope
- 2 Normative reference documents
- 3 Terms and definitions

Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009. Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This standard is proposed by the State Food and Drug Administration. This standard is nationalized by the National Standardization Subcommittee for Medical Optics and Instruments (SAC/TC103/SC1). The drafting of this standard unit. Zhejiang Medical Device Testing Institute. The main drafters of this standard. Huang Dan, Du Kun, Jia Xiaohang, Ye Yue Shun, Ye Zhongchen, Kong Peng. Laser treatment equipment Pulse doped neodymium yttrium aluminum garnet laser treatment machine

1 Scope

YY 1300 is the mandatory Chinese standard for pulsed Nd:YAG therapeutic lasers. At 1064 nanometres the beam penetrates deeper than most therapeutic wavelengths, which is why these lasers are used for vascular lesions, hair removal on darker skin and deep tissue work where a more superficial wavelength would not reach. Depth of penetration is also what makes the eye hazard severe, since the wavelength is invisible and transmitted to the retina. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering output energy and pulse duration and their accuracy, the delivery system, the aiming beam, the interlocks and the protective eyewear specification. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the terms and definitions of the pulsed neodymium-doped yttrium aluminum garnet (Nd: YAG) laser treatment machine, the basic parameters, requirements, test Law, sampling and marking, labeling, packaging and other requirements. This standard applies to the wavelength of 1064nm free oscillation pulse doped neodymium yttrium aluminum garnet laser treatment machine (hereinafter referred to as the treatment machine). The therapeutic function of the biological tissue condensation, vaporization, carbonation, melting. This standard does not apply to Q-switch neodymium-doped yttrium aluminum garnet laser treatment machine.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article. For undated references, the latest edition (including all modifications) applies to this document.

GB/T 191 packaging and storage icon

GB 7247.1 Safety of laser products - Part 1. Classification of equipment, requirements
Medical electrical equipment - Part 1. General requirements for safety GB 9706.1

GB 9706.19-2000 Medical electrical equipment - Part 2. Particular requirements for
endoscopic equipment safety

GB 9706.20 Medical electrical equipment - Part 2. Diagnostic and therapeutic requirements
for laser equipment safety Environmental requirements and test methods for medical
appliances GB/T

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation and testing in
risk management Methods for testing the main parameters of laser goggles

GB/T 17736-1999 General requirements for laser fiber for therapeutic use

YY/T 0758 General technical condition of

YY 1057 medical foot switch

ISO 11146 Laser and laser-related equipment Laser beam width, divergence angle and
beam transmission ratio test method (Laser and
laser-related equipment-Test methods for laser beam parameters-Beam widths,
divergence angle and beam propagation factor)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Pulse full width pulse duration The time difference between the rising edge of the pulse
and the end of the falling edge.

3.2 Pulse full width pulse train duration tau string The time difference between the rising
edge of the first sub-pulse in the burst and the end of the falling edge of the last sub-pulse.