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

YY 1301-2016

**Therapeutic laser equipment - Er: YAG laser equipment for
therapy**

激光治疗设备 钕激光治疗机

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Foreword

The technical content of this standard is mandatory. 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 release of this document The Agency does not assume responsibility for identifying 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. Ye Yueshun, Du Kun, Jia Xiaohang, Han Jiancheng, Sun Yu. Laser treatment equipment erbium laser treatment machine

1 Scope

YY 1301 is the mandatory Chinese standard for Er:YAG therapeutic lasers. The erbium wavelength is absorbed almost entirely by water, which means it ablates a very thin layer of tissue and leaves little thermal damage beneath: that makes it the laser of choice for skin resurfacing and for dental hard tissue work. The precision cuts both ways, since ablation begins immediately at the surface with little margin for error. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering the output energy and pulse characteristics, the beam delivery system, the aiming beam, and the interlocks and eye protection. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the basic parameters and product composition of erbium (Er. YAG) laser treatment machine, technical requirements, test methods and marking standards Sign, packaging and other requirements. This standard applies to erbium (Er. YAG) laser treatment machine with a wavelength of 2.94μm (hereinafter referred to as treatment machine). The treatment machine is erbium Light pulse on human tissue vaporization, carbonation and coagulation, to achieve the purpose of treatment.

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 9706.20 Medical electrical equipment - Part 2. Diagnostic and therapeutic requirements
for laser equipment safety Environmental requirements and test methods for medical
appliances GB/T Biological evaluation of medical devices - Part 1. Biological evaluation of
medical devices

GB/T 16886.1 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-

1 Laser and laser-related equipment - Test methods for laser beam width, divergence angle
and beam transmission ratio - Part

1 Points. no astigmatism and simple astigmatism
(Lasers and laser-related equipment test methods for laser beam widths, di-
vergence angles and beam propagation ratios - Part 1. Stigmatic and simple astigmatic beams)
ISO 11146-

2 Laser and laser-related equipment - Test methods for laser beam width, divergence angle
and beam transmission ratio - Part

2 Points. generalized astigmatism 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 Laser and laser-related equipment - Test method for laser beam width, divergence angle
and beam transmission ratio. Part. Intrinsic and geometric laser beam classification,
transmission and detailed test method (Lasers and laser-related equipment - Test
methods for laser beam widths, divergence angles and beam propagation ratios - Part 3. Intrinsic and
geometric laser beam classification, propagation and details of test methods)

3 Product composition and basic parameters

3.1 part of the treatment machine Treatment machine components.

a) erbium (Er. YAG) lasers;

b) laser power and control systems;

c) laser transmission system;

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