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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0983-2016

Therapeutic laser equipment - Ruby laser equipment for therapy

激光治疗设备 红宝石激光治疗机

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Table of Contents

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 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. Zhejiang Medical Devices Testing Institute, Tianjin Tian Da Precision Technology Co., Ltd. The main drafters of this standard. Du Kun, Ye Yue Shun, Sa Yu, Ye Zhisheng, Ren Guoquan. Laser treatment equipment ruby laser treatment machine

1 Scope

YY 0983 is the mandatory Chinese standard for ruby laser therapy equipment. The ruby laser at 694 nanometres is strongly absorbed by melanin, which makes it effective on blue and black tattoo pigment and on pigmented lesions where longer wavelengths are less selective. The same absorption is why it carries a high risk of depigmentation in the darker skin types common across much of the Chinese population, and why the parameters have to be controlled tightly. 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 delivery system, the aiming beam, the interlocks and the eye protection. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the composition and basic parameters, requirements, test methods, inspection rules and standards of the ruby (Cr3. Al2O3) laser treatment machine. Chi, labels, packaging and other requirements. This standard applies to the wavelength of 694.3nm ruby laser treatment machine (hereinafter referred to as treatment machine). The treatment machine utilizes ruby lasers The principle of selective light and heat, for the surface 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 Pieces. 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

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

GB/T 26599.1 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 General technical conditions for medical foot switch

3 Composition with basic parameters

3.1 composition of the treatment machine The composition of the treatment machine is as follows:

b) laser power supply;

c) beam transmission system;

d) control and safety protection systems;

e) cooling system;

f) application of accessories (including application of hand tools, etc.);

g) aiming optical device (if any);

h) Other accessories (which may include goggles, foot switches, etc.).

3.2 basic parameters of the treatment machine The manufacturer shall list the following basic parameters in the registered product standard.

a) treatment of laser wavelength;