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

YY 1289-2022

Replacing YY 1289-2016

Laser treatment equipment - Ophthalmic laser photocoagulator

激光治疗设备 眼科激光光凝仪

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1. Structure and Drafting Rules for Standardization Documents" drafting. This document replaces YY 1289-2016 "Ophthalmic Semiconductor Laser Photocoagulation Instrument for Laser Therapy Equipment". Compared with YY 1289-2016, In addition to structural adjustment and editorial changes, the main technical changes are as follows:

- Changed the "scope" (see Chapter 1, Chapter 1 of the.2016 edition);
- Changed the "normative references" (see Chapter 2, Chapter 2 of the.2016 edition);
- Changed the "terms and definitions" (see Chapter 3, Chapter 3 of the.2016 edition);
- Changed the "peak wavelength" (see 5.1.1, 5.1.1 of the.2016 edition);
- Changed the "pulse characteristics" (see 5.1.5, 6.1.5, 5.1.5, 6.1.5 of the.2016 edition);
- Changed the "control of terminal output power (or energy)" (see 5.1.6, 6.1.6, 5.1.6, 6.1.6 of the.2016 edition);
- Added "foot switch (if applicable)" (see 5.4, 6.4);
- Deleted the inspection rules, signs, labels, instructions for use, packaging, transportation and storage (see Chapter 7, Chapter 8, Chapter 8 of the.2016 edition Chapter 9). Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is sponsored by the National Optical and Photon Standardization Technical Committee Medical Optics and Instruments Sub-Technical Committee (SAC/TC103/SC1) Focus on. The previous versions of the

documents replaced by this document are as follows:

---YY 1289-2016. Laser Therapy Equipment Ophthalmic Laser Photocoagulation

1 Scope

YY 1289 is the mandatory Chinese standard for ophthalmic laser photocoagulators, the lasers used to seal retinal tears, treat diabetic retinopathy and perform panretinal photocoagulation. It sets the requirements such equipment has to meet and the test methods that verify them, covering the output power and its accuracy, the exposure duration, the spot size delivered at the retina, the aiming beam, and the interlocks and filters that protect the surgeon looking down the same optical path as the treatment beam. Diabetic retinopathy is a leading cause of blindness in China and photocoagulation is its mainstay treatment. The 2022 edition replaces YY 1289-2016 and takes effect in November 2025. Being a YY standard without the /T suffix, compliance is compulsory.

This document specifies the terms and definitions, product composition, requirements, test methods, etc. of ophthalmic laser photocoagulation apparatus (hereinafter referred to as photocoagulation apparatus). This document is applicable to equipment for clinical fundus laser photocoagulation therapy.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 7247.1 Safety of Laser Products Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Photocoagulation photocoagulation Due to the absorption of light radiation, the proteins in biological tissues are thermally denatured.

3.2 Spot diameter spotdiameter When measured in air, the diameter of the smallest circular area containing 86.5% of the radiant power [that is, the light intensity within the irradiation range of the spot along the diameter The diameter value when it is reduced to 1/e² (13.5%) of the center].

4 Product Composition

A photocoagulator should at least contain the following components.

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