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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0323-2024

Replacing YY 0323-2018

Infrared ray cauterization therapy equipment

红外热灼治疗设备

Issued on: February 7, 2024 **Implemented on: March 1, 2025**

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Preview: page 1 of 4 shown, 7 in the full document. Complete English PDF, instant download:
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Table of Contents

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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 0323-2018 "Special Safety Requirements for Infrared Therapy Equipment". Compared with YY 0323-2018, in addition to structural adjustments In addition to editorial changes, the main technical changes are as follows:

Preview: page 2 of 4 shown, 7 in the full document. Complete English PDF, instant download:
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--- Changed the terms and definitions of infrared thermal therapy equipment and irradiation gun (see 3.1, 3.2, 2.1.101,

2.1.102 of the.2018 edition);

--- Added terms and definitions of light source equipment (see 3.3);

--- Deleted the application part of terms and definitions (see

2.1.5 of the.2018 edition);

--- Changed the timing deviation of the timing device (see 4.3,

51.103 of the.2018 edition);

--- Changed the requirements for accompanying documents (see 4.5,

6.8.2 of the.2018 edition);

--- Added environmental test requirements and test methods (see 4.7, 5.7);

--- Added requirements and test methods for LS equipment (see 4.9, 5.9);

--- Deleted the requirements for classification (see Chapter 14 of the.2018 edition);

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1 Scope

YY/T 0323 applies to infrared thermal cauterization equipment, devices that use focused infrared energy to coagulate or destroy tissue in outpatient treatment. It specifies the requirements for such equipment and describes the corresponding test methods, covering how the device delivers and controls thermal energy and the checks that demonstrate it does so safely. The document replaces YY 0323-2018, and the change of prefix matters as much as the change of year: the standard has moved from mandatory to recommended, which alters how it is invoked in a registration dossier without making it any less the reference a Chinese reviewer applies. For a manufacturer of infrared therapy devices this is the product-specific text that sits alongside the general electrical safety standards of the YY 9706 series.

This document specifies the requirements for infrared thermotherapy equipment (hereinafter referred to as "equipment") and describes the corresponding test methods. This document applies to infrared thermal therapy equipment. This document does not apply to infrared laser therapy equipment.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced

Preview: page 3 of 4 shown, 7 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/yy-t-0323-2024

documents without a date, the latest version (including all amendments) applies to This document.

GB/T 5465.2-2008 Graphical symbols for electrical equipment Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Using the thermal effect of infrared radiation, the irradiated tissue undergoes denaturation and/or coagulation in a short period of time. Equipment used to treat patients.

3.2 Lightup gun A component used to output infrared radiation.

3.3 Light source equipment (LS equipment) lightsourceequipment Contains one or more non-laser optical radiation sources with a wavelength range of.200nm~3000nm, which produce non-visible Medical electrical devices for therapeutic, diagnostic, monitoring, plastic/cosmetic or veterinary applications. [Source: YY 9706.257-2021,.201.3.208]

4.1 Output Power

4.1.1 The output power may be indicated in absolute or relative units. For relative indication, do not use units that may differ from the actual output power.

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Preview: page 4 of 4 shown, 7 in the full document. Complete English PDF, instant download:
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