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

YY 0306-2023

Replacing YY 0306-2018

**General technical requirements for heat radiation therapy
equipment**

热辐射类治疗设备通用技术要求

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Table of Contents

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

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents" Drafting. This document replaces YY 0306-2018 "Special Safety Requirements for Thermal Radiation Treatment Equipment". Compared with YY 0306-2018, except for the structure In addition to adjustments and editorial changes, the main technical changes are as follows:

---Changed the description of the scope (see Chapter 1, Chapter 1 of the.2018 edition);

---Changed the definitions of thermal radiation, radiators, and thermal radiation treatment equipment (see 3.1, 3.2, 3.3,

2.1.101 of the.2018 edition, 2.1.102, 2.1.103);

---Deleted the term and definition thermal protection (see

2.1.104 of the.2018 edition);

---Added terms and definitions of emissivity (see 3.4);

---Deleted the classification (see Chapter 5 of the.2018 edition);

--- Added requirements and test methods for radiation characteristics (see 4.1, 5.1);

---Changed the requirements and test methods of the general provisions (see 4.3.1, 5.3.1, 34 of the.2018 edition);

---Deleted some requirements and test methods for changes to the general standard clauses (14.6, 24.103, 42.3,.2018 version) 42.5, 44.7, 51.101). Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the Physical Therapy Equipment Sub-Technical Committee of the National Medical Electrical Standardization Technical Committee (SAC/TC10/SC4). The previous versions of the standard replaced by this document are as follows:

---First released as YY 0306-1998 in.1998, revised for the first time in.2008, and revised for the second time in.2018;

---This is the third revision. General technical requirements for thermal radiation treatment equipment

1 Scope

YY 0306 is the mandatory Chinese general standard for heat radiation therapy equipment, the infrared and radiant heat devices used in physiotherapy, rehabilitation and traditional Chinese medicine practice. It sets the general requirements such equipment has to meet and the test methods that verify them, covering the radiant output and its distribution, the temperature reached at the treated surface, the timing and control of the exposure and the protections that prevent a burn. These devices are simple, cheap and used in enormous numbers in Chinese clinics, which is exactly why a mandatory floor exists: the hazard is thermal injury to a patient who may not be able to move away. The 2023 edition replaces YY 0306-2018 and takes effect in September 2026.

83.Special requirements for basic safety and basic performance of household phototherapy equipment

YY 9706.102 Medical electrical equipment Part 1-

2.General requirements for basic safety and basic performance Parallel standards.
Electromagnetic and Capacity requirements and testing

YY 9706.111 Medical electrical equipment Part 1-

11.General requirements for basic safety and basic performance Collateral standards. in the home Requirements for medical electrical equipment and medical electrical systems used in care environments

YY 9706.257 Medical electrical equipment Part 2-

57.Non-laser light sources for treatment, diagnosis, monitoring and plastic surgery/medical cosmetology Specific requirements for basic safety and basic performance of equipment

2 Normative reference documents

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

GB/T 7287-2008 Infrared radiation heater test method

GB 9706.1-2020 Medical electrical equipment Part

GB 9706.283 Medical electrical equipment Part 2-

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 heat radiationheatradiation The process of transferring energy in the form of electromagnetic waves resulting from thermal motion.

3.2 radiatorradiator Components that have strong thermal radiation capabilities and are not in direct contact with the human body during use can effectively convert the heat energy they absorb into thermal radiation. Radiated energy (electromagnetic waves). Note

1.If the radiator is in direct contact with the patient, the main way of energy exchange between the radiator and the patient is heat conduction rather than heat radiation, for example, if it has an infrared coating Materials for heating pad and foot stove. Other parts other than the radiator (such as protective covers other than the radiator) may be in contact with the human body or in use according to design requirements. not in contact.