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

YY/T 1306-2024

Replacing YY/T 1306-2016

Steam therapy apparatus

熏蒸治疗仪

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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/T 1306-2016 Fumigation Therapy Device. Compared with YY/T 1306-2016, except for structural adjustments and editorial changes, In addition to the above, the main technical changes are as follows:

- Changed the terms and definitions of closed fumigation and open fumigation (see 3.2, 3.3, 3.2, 3.3 of the.2016 edition);
- Added terms and definitions for steam generator (see 3.4);
- Changed the classification content (see Chapter 4, Chapter 4 of the.2016 edition);
- Deleted working conditions (see 5.1 of the.2016 edition);
- Changed the requirements for fumigation temperature (see 5.1, 5.2 of the.2016 edition);
- Changed the requirements for anti-dry burning function (see 5.3, 5.4 of the.2016 edition);
- Changed the requirements for safety protection functions (see 5.4, 5.5 of the.2016 edition);

1 Scope

YY/T 1306 is the product standard for the steam therapy apparatus, the fumigation device used in traditional Chinese medicine to deliver medicated vapour to the body or a part of it. It specifies the requirements for these instruments and the corresponding test methods. The safety case is straightforward and unforgiving: the device produces hot vapour close to skin, so temperature control, the accuracy of the setting, and the behaviour of the system if control fails are what separate a therapy from a burn. The 2024 edition takes effect on 20 July 2025. For a manufacturer or an exporter of fumigation and steam therapy units, including the domestic-use products that reach Western markets, this is the Chinese standard the equipment has to meet.

This document specifies the classification and requirements of fumigation therapy devices (hereinafter referred to as "therapeutic devices") and describes the corresponding test methods. This document applies to fumigation therapy devices (without medicine).

2 Normative references

The contents of the following documents constitute 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 documents without a date, the latest version (including all amendments) applies to This document.

GB 9706.1 Medical electrical equipment Part

3 Terms and definitions

The terms and definitions defined in GB 9706.1 and the following apply to this document.

3.1 A medical electrical device with temperature control function that generates steam by heating the liquid medicine to fumigate the affected area.

3.2 Closed steam therapy The steam and treatment area are isolated from the surrounding environment.

3.3 Open steam therapy Both the steam and the treatment area are exposed to the surrounding environment.

3.4 steam generator The device for vaporizing medicinal liquid consists of a heating unit and a decoction container.

4 Categories

According to the treatment part, it is divided into local treatment device and systemic

treatment device. According to the treatment method, it is divided into open and closed treatment devices. Figure 1, Figure 2 and Figure 3 show schematic diagrams of three types of therapeutic apparatuses.

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