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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 1539-2025

Replacing YY/T 1539-2017

Medical clean bench

医用洁净工作台

Issued on: October 30, 2025 **Implemented on: November 1, 2027**

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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/T 1539-2017 "Medical Clean Benches". Compared with YY/T 1539-2017, the only changes are structural adjustments and editing. Aside from the sexual alterations, the

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main technical changes are as follows:

---The description of the scope has been changed (see Chapter 1, Chapter 1 of the.2017 edition);

---The definitions of the terms "clean bench," "work area," "product protection," "high-efficiency filter," and "effective flow rate range" have been changed and will be... "High-efficiency filter" has been changed to "High-efficiency air filter" (see 3.1, 3.4, 3.5,

3.6 and 3.7, and 3.1, 3.4,

3.5 in the.2017 edition).

---The technical details of "Materials" have been changed (see 5.2.1,.2017 version 5.2.1);

---The technical details regarding the "enclosure" have been revised, and technical requirements for the installation location of the "lighting fixture" have been added (see 5.3.1.1, 5.3.1.3, and 5.3.1.6). (and 5.3.1.7, 5.3.1.1,

5.3.1.6 of the.2017 version);

---The headings for "Glass Window Operating Port (if any)", "Glass Window Operating Port Alarm System", and "Wind Speed Display" have been changed (see 5.3.2). Versions

5.3.9 and 5.3.10 (versions 5.3.2, 5.3.9, and

5.3.10 from the.2017 edition);

---The technical details regarding "illuminance" have been changed (see 5.4.3,.2017 version 5.4.3);

---The heading and technical content of the "Product Protection (Settling Bacteria)" section have been changed (see 5.4.5,.2017 version 5.4.5);

1 Scope

YY/T 1539 is the product standard for the clean bench used in medical settings. It gives the types of medical clean bench, specifies the requirements together with the labelling, accompanying documents, packaging, transport and storage, and describes the corresponding test methods. A clean bench is the workstation that protects the product, and in some configurations the operator, by pushing filtered air across the work surface, so its qualification turns on airflow, filtration and containment performance rather than on the cabinet itself. The 2025 edition carries an unusually long run-in, taking effect on 1 November 2027, which gives manufacturers two years to bring existing models into line. For a manufacturer or an importer of clean benches for hospital pharmacies, laboratories or device production, this is the standard the Chinese registration test is run against.

This document defines the types of medical clean benches (hereinafter referred to as clean benches), and specifies the requirements, labeling and accompanying documents,

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packaging, and transportation. The contents and storage information are described, along with the corresponding experimental methods. This document applies to medical clean benches used in medical institutions.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 191 Pictorial Symbols for Packaging and Storage

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

GB/T 18268.1 Electromagnetic compatibility requirements for electrical equipment for measuring, control and laboratory use - Part

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3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Suitable for medical institutions, this box-type air purification system can provide local operating environments with a cleanliness level of ISO 5 (Class 100) or higher. equipment.

Note. Common names for clean benches include clean workbench, ultra-clean workbench, medical clean workbench, and biological clean workbench.

3.2 The airflow flows from top to bottom and is perpendicular to the horizontal plane.

3.3 The airflow moves from one side to the other, and the airflow is parallel to the horizontal plane.

3.4 working area The area where operations are performed inside the clean bench.

3.5 Product protection Clean benches prevent airborne contaminants from outside from entering the work area through the front window operating port.

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