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

YY/T 1610-2025

Replacing YY/T 1610-2018

Anaesthetic and respiratory equipment - Passive humidifiers

麻醉和呼吸设备 被动湿化器

(English Translation)

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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 1610-2018 "Medical Oxygen Humidifiers for Anesthesia and Respiratory Equipment" and is consistent with YY/T 1610-2018.

Compared to previous versions, aside from structural adjustments and editorial changes, the main technical changes are as follows.

- Gas flow and leakage specifications have been changed (see 4.3, 7.4 in the 2018 version);
- The requirements regarding appearance have been changed (see 5.1.1, Chapter 5 of the 2018 edition);
- The overflow requirements have been changed (see 5.1.4, 7.2 in the 2018 version);
- The overpressure requirement has been changed (see 5.1.5, Chapter 8 of the 2018 edition);
- The requirements for markings on the exterior of passive humidifiers or their components have been changed (see 6.2, Chapter 12, 2018 edition);
- The requirements for the instruction manual have been changed (see 6.4, Chapter 13 of the 2018 edition);
- The requirements for humidification output have been changed (see Chapter 7, 7.1 of the 2018 edition);
- The requirements for cleaning and disinfection have been changed (see Chapter 10,

Chapter 11 in the 2018 edition);

---The requirements for respiratory system connectors and ports have been changed (see Chapter 11, Chapter 6 of the 2018 edition);

---The compatibility requirements with materials have been changed (see Chapter 13, Chapter 4 in the 2018 edition);

---Water level requirements have been added (see 4.1);

---Added passive humidifier test conditions (see 4.2);

---Increased the testing error for passive humidifiers (see 4.4);

---Added requirements regarding instability caused by unnecessary lateral movements (see 5.1.2);

---The requirement for audible sound energy has been increased (see 5.1.3);

---Added compatibility requirements (see 5.2);

---General requirements for mechanical strength have been added (see 5.3);

---Requirements for units of measurement have been added (see 6.3);

---Added technical specification requirements (see 6.5);

---Added system requirements (see Chapter 8);

---Added specific single fault states (see Chapter 9);

---Requirements for the respiratory system and accessories have been added (see Chapter 12);

---Biocompatibility requirements have been added (see Chapter 14);

---Fire protection requirements have been added (see Chapter 15);

---Availability requirements have been added (see Chapter 16);

---The requirement for pressure relief has been removed (see 7.3 in the 2018 version);

---The requirement for residual ethylene oxide has been removed (see section 10.3 of the 2018 edition);

---The requirement for microbial limits has been removed (see 10.4 in the 2018 edition).

This document is modified to adopt ISO 20789:2018 "Passive humidifiers for anesthesia and respiratory equipment".

The technical differences between this document and ISO 20789:2018, and the reasons therefor, are as follows.

---ISO 7396-1:2016 has been replaced with the normatively referenced GB/T 44059.1-2024