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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 46042-2025

**Anaesthetic and respiratory equipment - Low-pressure hose
assemblies for use with medical gases**

麻醉和呼吸设备 医用气体低压软管组件

(English Translation)

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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 is modified to adopt ISO 5359:2014 "Medical gas low-pressure hose assemblies for anesthetic and respiratory equipment".

The technical differences between this document and ISO 5359:2014 and their reasons are as follows.

--- ISO 14971 (see 4.1, 4.4) is replaced by the normative reference GB/T 42062 to adapt to my country's technical conditions;

--- ISO 1307 (see 4.6.1.3) is replaced by the normative reference GB/T 9575 to adapt to my country's technical conditions;

--- ISO 8033 (see 4.6.5) is replaced by the normative reference GB/T 14905 to adapt to my country's technical conditions;

--- ISO 9170-1 (see 4.6.8) is replaced by the normative reference GB/T 45898.1 to adapt to my country's technical conditions;

--- ISO 15001 (see 4.7.1) is replaced by the normative reference GB/T 45899 to adapt to my country's technical conditions;

--- ISO 1402 (see 5.6) is replaced by the normative reference GB/T 5563 to adapt to my country's technical conditions;

--- Deleted the normative reference ISO 14155 (see 4.3 of ISO 5359:2014) to adapt to my country's technical conditions;

--- Deleted the requirements for DISS and SIS connectors (see 1.3, 3.4, 4.6.8 of ISO 5359:2014) to adapt to my country's technology condition;

--- Changed the requirements for clinical evaluation (see 4.3) to adapt to my country's technical conditions;

--- Changed the test method for durability of marking and color identification (see 5.8) to adapt to my country's technical conditions;

--- Deleted the color identification requirements of other regional or national standards (see 6.2.1 of ISO 5359:2014) to adapt to my country's technology condition.

The following editorial changes have been made to this document.

--- Incorporated the amendments to ISO 5359:2014/Amd1.2017, the outer margins of the clauses involved are indicated by vertical Double lines (||) are marked;

- Replaced ISO 9170-1 with the informative reference GB/T 45898.1 (see Chapter 1);
- Replaced ISO 18082 with the informative reference GB/T 45895 (see Chapter 1);
- Replaced IEC 60601-1-6 with the informative reference YY/T 9706.106-2021, and replaced IEC 62366 with YY/T 1474 (see 4.2);
- Replaced ISO 15001 with the informative reference GB/T 45899 (see 4.5.1);
- Replaced ISO 1402 with the informative reference GB/T 5563 (see 5.5.1);
- Deleted the unreferenced terms "accompanying documents", "basic safety", "maximum working pressure", "medical gas pipeline system", "non-interchangeable threaded joints" and "93% oxygen" (see 3.2, 3.3, 3.13, 3.15, 3.16 and 3.19 of ISO 5359:2014);
- Deleted the content of the note (see 4.3 of ISO 5359:2014).

Introduction

This document was developed because there is a need for a safe method of connecting medical equipment to a fixed medical gas piping system or Other medical gas supply systems to meet the requirement that hose assemblies conveying different gases or the same gas at different pressures cannot be interchanged.

Once the fixed medical gas pipeline is installed, it cannot be moved at will and must be used in accordance with the prescribed procedures to prevent cross mixing of medical gases.

However, in a relatively short period of use, hose assemblies are frequently connected to medical equipment and fixed gas pipelines.

Connecting and disconnecting are subject to wear, tear, misuse and abuse.

While recognizing that no system is completely safe, this document contains information to prevent foreseeable hazards arising from the use of hose assemblies.

The operator must always be alert to the possibility of damage caused by external factors. Therefore, regular inspections and maintenance are required to ensure that Ensure that the hose assembly continues to meet the requirements of this document.

This document focuses in particular on.

- Material suitability;
- Gas specificity;
- Prevent cross connection;
- clean;
- test;

---Identification;

---Information provided by the manufacturer.

ISO 17256 covers the requirements for respiratory therapy circuits and refers to ISO 80369-2 for small-bore breathing systems and drive gases.

Requirements for connectors.

In order to avoid the danger of cross-mixing between components of different gases and to facilitate the connection between components of the same gas, this document only allows the use of NIST (non-interchangeable thread system) connectors specified in GB/T 45895.

Medical gas low-pressure hose assemblies for anesthesia and respiratory equipment

1 Scope

This document specifies the use of oxygen, nitrous oxide (laughing gas), medical air, helium, carbon dioxide, xenon, and specific mixtures of these gases.

Requirements for low-pressure hose assemblies for medical gases such as 93% oxygen, air for driving surgical instruments, nitrogen for driving surgical instruments, and vacuum.

This document applies to hose assemblies with a working pressure not exceeding 1400kPa and vacuum system hose assemblies with an absolute pressure not exceeding 60kPa.

This document does not specify the size and configuration of gas-specific inlet and outlet fittings for hose assemblies.

Note 1: The dimensions and configurations of non-interchangeable threaded (NIST) fittings are specified in GB/T 45895.

Note 2: Terminals designed for quick connectors are specified in GB/T 45898.1.

This document does not specify requirements for coaxial hoses used for the supply and exhaust of air used to drive surgical instruments.

This document does not specify the intended use of the hose assembly.

Note 3: For environmental factors, see Appendix B.

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