

ICS 11.040.10

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

GB/T 45897.2-2025

**Pressure regulators for use with medical gases - Part 2:
Manifold and line pressure regulators**

医用气体压力调节器 第2部分：汇流排压力调节器和管道压力调节器

(English Translation)

Issued on: August 1, 2025

Implemented on: August 1, 2026

**Issued by: State Administration for Market Regulation, Standardization
Administration of China**

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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 Part 2 of GB/T 45897 "Medical gas pressure regulators". GB/T 45897 has been published in the following parts.

- Part 1: Pressure regulators and pressure regulators with flow meters;
- Part 2: Busbar pressure regulator and pipeline pressure regulator;
- Part 3: Pressure regulators with integrated cylinder valves (VIPRs);
- Part 4: Low pressure regulators.

This document is modified to adopt ISO 10524-2:2018 "Medical gas pressure regulators - Part 2: Busbar pressure regulators and pipeline pressure regulators" Force Regulator.

The technical differences between this document and ISO 10524-2:2018 and their reasons are as follows.

- ISO 14971 (see 5.1) is replaced by the normative reference GB/T 42062 to adapt to my country's technical conditions;
- ISO 15001 (see 5.1, 7.1) is replaced by the normative reference GB/T 45899 to adapt to my country's technical conditions;
- EN837-1 (see 6.2.1, 6.2.4, 6.2.7) has been replaced with the normative reference GB/T 1226-2017 to adapt to my country's technical requirements.

Technical conditions;

- Replaced IEC 60601-1 (see 6.3) with the normative reference GB 9706.1 to adapt to my country's technical conditions;
- Replaced ISO 10297 (see 8.1.2) with the normative reference GB/T 15382-2021 to

adapt to my country's technical conditions;

--- Added the requirement for ethanol volume fraction (see 8.6) to adapt to my country's technical conditions;

--- ISO 32 (see 9.1.1) is replaced by the normative reference GB 50751 to adapt to my country's technical conditions;

--- Deleted "If the manufacturer does not have a local address, the responsible party may refer to the local authorized representative." (See ISO 10524-2.

2018, 10.1), to adapt to my country's technical conditions;

--- Replaced ISO 7396-1 (see 10.2) with the normative reference GB/T 44059.1 to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

--- Deleted some notes related to regional or national standards;

--- Replaced ISO 15001 with the informative reference GB/T 45899 (see 5.4.1, 5.4.2, 7.2);

--- Replaced IEC 60529 with the informative reference GB/T 4208 (see 6.2.2);

--- Changed the errors in the reference clauses (see 6.6, 8.3.7, 8.4.3, 8.5);

--- Delete the subscripts of some gases in Table 5 and add relevant instructions;

--- Replaced ISO 10297 with the informative reference GB/T 15382-2021 (see 8.3.8.1);

--- Replaced ISO 10524-1 with the informative reference GB/T 45897.1 (see B.6.5.1);

--- Deleted the appendix "Differentiations in color coding and naming of medical gases in different regions and countries" (see ISO 10524-2:2018 Appendix C).

Introduction

GB/T 45897 "Medical gas pressure regulators" is intended to consist of four parts.

--- Part 1: Pressure regulators and pressure regulators with flow meters. The purpose is to specify the pressure regulators intended for patient treatment, Pressure regulators for the management of medical gases and their mixtures for the treatment, diagnosis, evaluation and nursing of medical equipment or for the management of gases used to drive surgical instruments Design, construction, type testing and marking requirements.

--- Part 2: Busbar pressure regulators and pipeline pressure regulators. The purpose is to specify the intended use for medical gas pipeline systems Design, structure, type test and marking requirements for bus pressure regulators and pipeline pressure regulators.

--- Part 3: Pressure regulators with integrated cylinder valves (VIPRs). The purpose is to specify the pressure regulators intended for use in the treatment, management, diagnosis

and treatment of patients.

A device with an integrated gas cylinder valve pressure regulator for the management of medical gases or gases used to drive surgical instruments for diagnostic assessment and care Design, type testing and marking requirements.

--- Part 4: Low pressure regulators. The purpose is to specify the low pressure regulators for oxygen, nitrous oxide (laughing gas), medical air, helium, dioxygen Carbon dioxide, xenon and specific mixtures of the above gases, air for driving surgical instruments, nitrogen and oxygen-enriched air for driving surgical instruments Specification for low-pressure regulators for use in conjunction with this standard for patient treatment, management, diagnostic evaluation, and care.

The busbar pressure regulator is used to reduce the pressure of gas cylinders to a lower pressure as the gas source pressure for medical gas pipeline systems.

The pipeline pressure regulator is used to reduce the pressure generated by the busbar pressure regulator or low-temperature container to a lower pressure as a medical gas the pressure at the end of the pipe system.

These functions cover a range of inlet and outlet pressures and flows and therefore require specialized design features.

It is important that the operating characteristics of busbar pressure regulators and line pressure regulators are specified and tested in a clear manner.

It is essential to ensure that the pressure regulator continues to meet the requirements of this document through regular inspection and maintenance.

This document focuses in particular on.

---Material suitability;

---Safety (mechanical strength, leakage, safe discharge in case of overpressure and flame retardancy);

---Cleanliness;

---Type test;

---Identification;

---Information provided by the manufacturer.

Appendix B contains the basic principles of some requirements of this document. The chapters and clauses marked with an asterisk (*) after the number have the corresponding basic principles.

This document provides the reasons for the requirements and recommendations of this document. Understanding the reasons for these requirements will not only help you to