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

GB/T 45897.1-2025

**Pressure regulators for use with medical gases - Part 1:
Pressure regulators and pressure regulators with flow-metering
devices**

医用气体压力调节器 第1部分：压力调节器和带有流量计的压力调节器
(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 Part 1 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 10524-1:2018 "Medical gas pressure regulators Part 1: Pressure regulators and flowmeters Pressure Regulator.

The technical differences between this document and ISO 10524-1:2018 and their reasons are as follows.

--- Incorporate the contents of the nominal outlet pressure (p_2) into the notes (see 6.5.1.2);

--- ISO 14971 has been replaced by the normative reference GB/T 42062 to adapt to my country's technical conditions (see 5.1);

--- ISO 15001 has been replaced by the normative reference GB/T 45899 to adapt to my country's technical conditions (see 5.1, 7.1);

--- EN837-1 is replaced by the normative reference GB/T 1226 to adapt to my country's technical conditions (see 6.2.2);

--- Replaced IEC 60601-1 with the normative reference GB 9706.1 to adapt to my country's technical conditions (see 6.3);

--- ISO 5145 is replaced by the normative reference GB/T 15383 to adapt to my country's technical conditions (see 6.4.1);

--- Replaced ISO 9170 (all parts) with the normative reference GB/T 45898.1 to adapt to my country's technical conditions (see 6.4.2.3);

--- Replaced ISO 10297 with the normative reference GB/T 15382-2021 to adapt to my country's technical conditions (see 8.1.2, 8.2, 8.7.1, 8.14);

--- The normative reference GB 50751 replaces ISO 32 to adapt to my country's technical conditions (see 9.1.1);

--- Deleted the term "mastoid joint" which was used only once in the text (see 3.10 of ISO 10524-1:2018).

The following editorial changes have been made to this document.

--- Incorporated the amendments to ISO 10524-1:2018/Amd1.2023, and the outer margins of the clauses involved are marked with vertical Straight double lines (||) are marked;

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

--- Replaced ISO 15001 with the informative reference GB/T 45899-2025 (see 5.4.1, 5.4.2);

--- Replaced IEC 60529 with the informative reference GB/T 4208 (see 6.2.2.2);

--- Delete the subscripts of some gases in Table 4 and add relevant instructions (see 9.1.1);

--- Replaced ISO 7396-1 with the informative reference GB/T 44059.1 (see A.6.5, A.6.10);

--- Deleted the appendix "Reported regional and national differences in colour identification and terminology for medicinal gases" (see ISO 10524-1.

Appendix B of 2018).

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 in 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.

Pressure regulators are used to reduce cylinder pressure to a lower pressure suitable for use in medical devices or for delivering gas directly to patients.

These functions involve a wide range of pressures and flows at both the inlet and outlet ports and therefore require specialized design features.

It is important to specify and test the operating characteristics of the pressure regulator.

Pressure regulators are usually equipped with a device to control the flow, such as a flow control device or a fixed orifice. The flow rate can be measured using a flow meter or flow meter.

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