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

**GB/T 45897.4-2025**

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**Pressure regulators for use with medical gases - Part 4:  
Low-pressure regulators**

医用气体压力调节器 第4部分：低压压力调节器

**(English Translation)**

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## Table of Contents

|                                                                                                     |  |
|-----------------------------------------------------------------------------------------------------|--|
| Preface                                                                                             |  |
| Introduction                                                                                        |  |
| 1 Scope                                                                                             |  |
| 2 Normative references                                                                              |  |
| 3 Terms and Definitions                                                                             |  |
| 4 Naming                                                                                            |  |
| 5 General Requirements                                                                              |  |
| 5.1 Security                                                                                        |  |
| 5.2 Optional Structure                                                                              |  |
| 5.3 Materials                                                                                       |  |
| 5.4 Design Requirements                                                                             |  |
| 5.5 Assembly requirements                                                                           |  |
| 6 Test Method                                                                                       |  |
| 6.1 Overview                                                                                        |  |
| 6.2 Test conditions                                                                                 |  |
| 6.3 Gas outlet pressure test method                                                                 |  |
| 6.4 Leakage test method                                                                             |  |
| 6.5 Mechanical strength test method                                                                 |  |
| 6.6 Test method for flow accuracy of pressure regulator with flow meter or flow meter               |  |
| 6.7 Test method for flow stability of pressure regulators with flow meters or flow gauges           |  |
| 6.8 Test method for flow stability and accuracy of pressure regulators equipped with fixed orifices |  |
| 6.9 Disassembly torque test method                                                                  |  |
| 6.10 Test method for durability of marking and color identification                                 |  |
| 7 Marking, color coding and packaging                                                               |  |
| 7.1 Mark                                                                                            |  |
| 7.2 Color identification                                                                            |  |
| 7.3 Packaging                                                                                       |  |
| 8 Information provided by the manufacturer                                                          |  |
| Appendix A (Informative) Typical Examples of Low-Pressure Pressure Regulators                       |  |
| Appendix B (Informative) Basic Principles                                                           |  |
| Appendix C (Informative) Environmental Factors                                                      |  |

## Reference

## 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 4 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 10524-4:2008 "Medical gas pressure regulators - Part 4: Low-pressure pressure regulators".

The technical differences between this document and ISO 10524-4:2008 and their reasons are as follows.

- Replaced ISO 10524-1 (see 1.2, 5.4.1) with the normative reference GB/T 45897.1 to adapt to my country's technical conditions;
- Replaced ISO 10524-3 (see 1.2, 5.4.1) with the normative reference GB/T 45897.3 to adapt to my country's technical conditions;
- Replaced ISO 7396-1 (see 1.2, 5.1.2, 5.4.1) with the normative reference GB/T 44059.1 to adapt to my country's technology condition;
- ISO 14971 (see 5.1.1) is replaced by the normative reference GB/T 42062 to adapt to my country's technical conditions;
- Replaced ISO 5359 (see 5.4.3.2.3.2) with the normative reference GB/T 46042 to adapt to my country's technical conditions;
- ISO 15001 (see 5.5.1) is replaced by the normative reference GB/T 45899 to adapt to my country's technical conditions;
- EN837-1 (see 5.4.2.1, 5.4.2.2, 5.4.2.4) has been replaced with the normative reference GB/T 1226 to adapt to my country's technology condition;
- Replaced ISO 9170 (see 5.4.3.1, 5.4.3.2.3) with the normative reference GB/T 45898.1 to adapt to my country's technology condition;

- Replaced ISO 32 (see 5.4.3.2.3.3, 7.1.1) with the normative reference GB 50751 to adapt to my country's technical conditions;
- Added the requirements for ethanol volume fraction (see 6.10) to adapt to my country's technical conditions;
- Changed the pressure outlet requirements (see 5.4.3.2.3) to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

- Deleted some notes and statements related to regional or national standards (see 5.2, 5.3.2, 5.3.3, 5.3.6, 5.4.2.6, 5.4.7, 5.4.10.3, 5.4.12.2.1, 5.5.1, 5.5.2);
- Replaced ISO 14971 with the informative reference GB/T 42062 (see 5.2);
- Replaced ISO 15001 with the informative reference GB/T 45899 (see 5.3, 5.4.7);
- Replaced ISO 10524 (see 5.3.1) with the informative reference GB/T 45897 (all parts);
- Delete the subscripts of some gases in Table 2 and add relevant instructions (see 7.1.1);
- Deleted the appendix "Reported regional and national color coding deviations and medical gas terminology" (see ISO 10524-4:2008 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 requirements for pressure regulators with integrated cylinder valves for the treatment, management, Pressure regulators with integrated gas cylinder valves for the management of medical gases for diagnostic assessment and nursing care or for the management of gases used to drive surgical instruments 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.

Low pressure regulators are used to reduce the pressure in medical gas pipeline systems to a level suitable for use with medical equipment or to supply gas directly to patients.

People deliver gas.

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

It is very important to specify and test the operating characteristics of low pressure regulators in a certain manner.

Low pressure regulators usually have a device to control the flow, such as a flow control device or a fixed orifice. The flow can be measured by a flow meter or flow Scale representation.

It is essential to ensure that low pressure regulators continue to meet the requirements of this document through regular inspection and maintenance.

This document focuses in particular on.

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

--- Suitability of materials;

---Gas specificity;

---Accuracy;

---Cleanliness;

---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.

Understanding the reasons for these requirements will not only help in the correct application of this document, but also will an asterisk (\*) at the beginning of a title, paragraph, or table indicates that there are related guidelines or Basic principles.

Medical gas pressure regulators Part 4: Low-pressure regulators