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

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**Pressure regulators for use with medical gases - Part 3:
Pressure regulators integrated with cylinder valves (VIPRs)
(English Translation)**

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This Document is Part 3 of GB/T 45897 Pressure Regulators for Use with Medical Gases. GB/T

45897 consists of the following parts.

- Part 1.Pressure regulators and pressure regulators with flow-metering devices;
- Part 2.Manifold and line pressure regulators;
- Part 3.Pressure regulators integrated with cylinder valves (VIPRs);
- Part 4.Low-pressure regulators.

This Document modified and adopted ISO 10524-3.2019 Pressure Regulators for Use with Medical Gases - Part 3.Pressure Regulators Integrated with Cylinder Valves (VIPRs).

The technical differences and causes between this Document and ISO 10524-3.2019 are as follows.

- Use the normative reference GB/T 42062 to replace ISO 14971 (see 5.1), so that adapt to China's technical conditions;
- Use normatively quoted GB/T 45899 to replace ISO 15001 (see 5.1, 7.1), so that adapt to China's technical conditions;
- Use normative reference GB 9706.1 to replace IEC 60601-1 (see 6.2), so that adapt to China's technical conditions;
- Use normative reference GB/T 15383 to replace ISO 5145.2004 (see 6.3.2), so that adapt to China's technical conditions;
- Use normative reference GB/T 8335 to replace ISO 11363-1 (see 6.4.1), so that adapt to China's technical conditions;
- Use normative reference GB/T 45898.1 to replace ISO 9170-1 (see 6.4.2.2), so that adapt to China's technical conditions;

--- Use normative reference GB/T 1226 to replace EN 837-1 (see 6.6.2.1), so that adapt to China's technical conditions;

--- Use normative reference GB/T 15382-2021 to replace ISO 10297 (see 6.9, 6.12.3, 6.13.1, 6.13.4, 8.1.1, 8.2, 8.6.2.1, 8.14.2, 9.3.1, 10.1.2), so that adapt to China's technical conditions;

--- Use normative reference GB 50751 to replace ISO 32 (see 10.1.1), so that adapt to China's technical conditions;

--- Change and add the test conditions for the oxygen pressure ignition test (see Tables 3 to 6), so that adapt to China's technical conditions and improve operability.

This Document made the following editorial modifications.

--- Delete some notes and statements referring to regional or national standards;

--- Replace ISO 15001 with the informative reference GB/T 45899 (see 5.3 and 7.2);

--- Replace EN 837-1 with the informative reference GB/T 1226 (see 6.6.2.1);

--- Replace ISO 10297 with the informative reference GB/T 15382-2021 (see 8.7.2 and B.6.1);

--- Supplement a pressure gauge and valve (reference numbers 6 and 7) to the "High-pressure flexible hose (short)" in Figure 5 to facilitate residual pressure measurement in 9.4.3;

--- Delete some gas superscripts and add relevant explanations (see 10.1.1 of ISO 10524-3:2019);

--- Delete the "Basic Principles" in the B.1 (see Annex B of ISO 10524-3:2019);

--- Delete the annex "Summary of regional and national differences in color coding and nomenclature for medicinal gases" (see Annex C of ISO 10524-3:2019).

Please note some contents of this Document may involve patents. The issuing agency of this

Document shall not assume the responsibility to identify these patents.

This Document was proposed by National Medical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on

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and Respiratory Equipment of Standardization Administration of China (SAC/TC 116).

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Pressure Regulators for Use with Medical Gases - Part 3.

Pressure Regulators Integrated with Cylinder Valves (VIPRs)

1 Scope

This Document specifies design, type testing, and marking requirements for cylinder valves with integrated pressure regulators [referred to hereafter as (VIPRs)] intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients or for gases used for driving surgical tools.

EXAMPLE. Gases include oxygen, medical air and oxygen/nitrous oxide (laughing gas) mixtures.

This document applies to VIPRs mounted on refillable cylinders with a working pressure up to

30 000 kPa (300 bar) intended to be filled in cylinder filling facilities or on self-filling systems as used in homecare applications.

VIPRs covered by this document are pressure pre-set and provided with a pressure outlet and/or

pre-set flow outlet(s).

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates