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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0893-2023

Replacing YY/T 0893-2013

Gas mixers for medical use - Standalone gas mixers

医用气体混合器 独立气体混合器

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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 replaces YY/T 0893-2013 "Medical Gas Mixer Independent Gas Mixer", and is consistent with YY/T 0893-2013 In addition to structural adjustments and editorial changes, the main technical changes are as follows:

- a) Changed the scope to indicate that this document applies to stand-alone gas mixers designed to mix oxygen with other medical gases, excluding An independent gas mixer connected to an oxygen concentrator (see Chapter 1, Chapter 1 of the:2013 edition);
- b) Changed the definition (see 3:8, 3:1 of the:2013 edition);
- c) Added basic performance requirements (see Chapter 4);
- d) increased risk management and usability (see 5:1 and 5:2);
- e) Added materials (see Chapter 6);
- f) Added the requirement for air inlet pressure (see Chapter 8);
- g) Changed the requirements for reverse airflow (see Chapter 9, Chapter 6 of the:2013

edition);

h) Added electric alarm system and non-electric alarm system (see 11:1 and 11:2);

i) Changed the requirements for the high-voltage alarm state (see 11:3, 5:2 of the:2013 edition);

j) Increased differential pressure alarm state (see 11:4);

k) Changed the requirements for the gas source failure alarm state (see 11:5, 12:1 of the:2013 edition);

l) The requirements for gas source failure have been changed (see Chapter 13, 12:2~12:5 of the:2013 edition);

m) A gas outlet fitting is added and the gas outlet fitting is specified for use with a stand-alone gas mixer with an integral flow controller (see 14:2);

1 Scope

YY/T 0893 covers the standalone medical gas mixer, the device that blends oxygen with air or another gas to a set concentration for delivery to a patient. It sets the requirements such a mixer has to meet and the test methods that verify them, covering the accuracy of the delivered concentration across the flow range, the behaviour when a supply gas fails, the alarms that warn of it, and the protection against delivering a hypoxic mixture. The mixer sits upstream of ventilators, resuscitaires and oxygen therapy devices, so an error in it propagates to whatever it feeds, and neonatal care in particular depends on delivering an exact oxygen fraction. The 2023 edition replaces YY/T 0893-2013. For a manufacturer this is the document a Chinese registration is assessed against.

This document specifies the performance and safety requirements for self-contained gas mixers intended to mix oxygen with another medical gas: This document does not apply to:

- a) Flow meter group with independent control of each gas flow;
- b) a separate gas mixer for mixing oxygen and ambient air;
- c) an independent gas mixer with more than two different gas inlets;
- d) A separate gas mixer connected to the oxygen concentrator:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 3767-2016 Acoustic sound pressure method Determination of sound power level of noise source and sound energy level Approximate free field above the reflecting surface Process method (ISO 3744:2010, IDT)

GB 9706.1-2020 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1: 2012, MOD)

Note: There is no technical difference between the referenced content of

GB 9706.1-2020 and the referenced content of IEC 60601-1:2012

GB 9706.255 Medical Electrical Equipment Part 2-55: Particular Requirements for Basic Safety and Essential Performance of Respiratory Gas Monitors (GB 9706.255-2022, ISO 80601-2-55:2018, MOD)

GB 50751 Technical Specifications for Medical Gas Engineering

YY/T 0316 Application of medical device risk management to medical devices (YY/T 0316-2016, ISO 14971:2007, IDT)

YY/T 0799 Medical gas low-pressure hose assembly (YY/T 0799-2010, ISO 5359:2008, MOD) YY 0801:

1 Terminals of medical gas piping system Part 1: Terminals for compressed medical gas and vacuum (YY 0801.1- 2010, ISO 9170-1:2008, MOD)

YY/T 0882 Compatibility of anesthesia and respiratory equipment with oxygen (YY/T 0882-2013, ISO 15001:2003, IDT)

YY 9706.108 Medical Electrical Equipment Part 1-8: General Requirements for Basic Safety and Essential Performance Collateral Standard: General Requirements Requirements, tests and guidelines for alarm systems in medical electrical equipment and medical electrical systems (YY 9706.108-2021,

IEC 60601-1-8: 2006/Amd1:2012, MOD) ISO 7396-