ICS 11.040.10
CCS C46

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.279-2023

Replacing YY 0600.1-2007

Medical electrical equipment - Part 2-79: Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory impairment

医用电气设备 第2-79部分：用于呼吸功能障碍的呼吸支持设备的基本安全和基本性能专用要求

Issued on: March 14, 2023 **Implemented on: May 1, 2026**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 14 March 2023 by the National Medical Products Administration and takes effect on 1 May 2026.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It is classified under ICS 11.040.10, Chinese classification C46.

It replaces YY 0600.1-2007, which is superseded.

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: "Medical Electrical Equipment" is divided into two parts:

--- Part 1: General and parallel requirements;

--- Part 2: Special requirements: This document is Part 2-79: YY 9706:279-2023 and YY 9706:280-2023 jointly replace YY 0600:1-2007: With YY 0600:1-2007 In comparison, the main technical differences are as follows:

--- Divide the scope covered by YY 0600:1-2007 into two parts: one for patients with respiratory dysfunction (YY 9706:279- 2023), and one for patients with respiratory insufficiency (YY 9706:280-2023);

--- Expand the scope to include respiratory support equipment and its accessories, where the characteristics of these accessories may affect the basic This safety or essential performance, not just respiratory support equipment itself;

--- Identify the basic performance of respiratory support equipment and its accessories;

--- Added respiratory ventilation performance requirements and tests;

--- Added requirements for mechanical strength test;

--- Added new symbols;

--- Increased the requirements for respiratory support equipment as part of the medical electrical system;

--- Added shell integrity test;

--- Added cleaning and disinfection procedure test;

--- Increased consideration of the contamination of the breathing gas delivered to the patient from the gas pathway: This document is modified to adopt ISO 80601-2-79:2018 "Medical Electrical Equipment Part 2-79: Respiratory devices for respiratory dysfunction Particular Requirements for Basic Safety and Essential Performance of Supporting Equipment": The technical differences between this document and ISO 80601-2-79:2018 and their reasons are as follows:

--- Replaced IEC 61672-1:2013 with the normatively quoted GB/T 3785:1 to adapt to the technical conditions of our country;

--- Replaced IEC 60601-1:2005 with the normatively quoted GB 9706:1-2020 to adapt to the technical conditions of our country;

--- Replaced ISO 80601-2-12 with the normatively quoted GB 9706:212 to adapt to the technical conditions of our country;

--- Replaced ISO 5367:2014 with the normative referenced YY/T 0461 to adapt to the technical conditions of our country;

--- Replaced ISO 15223-1:2016 with the normative reference YY/T 0466:1-2016 to adapt to the technical conditions of our country;

--- Replaced ISO 17510:2015 with the normative reference YY/T 0671-2021 to adapt to the technical conditions of our country;

--- Replaced ISO 9360-1:2000 with the normative referenced YY/T 0735:1 to adapt to the technical conditions of our country;

--- Replaced ISO 9360-2:2001 with the normative reference YY/T 0735:2 to adapt to the technical conditions of our country;

--- Replaced ISO 23328-1:2003 with the normative referenced YY/T 0753:1 to adapt to the technical conditions of our country;

--- Replaced ISO 17664:2017 with the normative reference YY/T 0802-2020 to adapt to the technical conditions of our country;

--- Replaced ISO 80369-1:2010 with the normative reference YY/T 0916:1 to adapt to the technical conditions of our country;

--- Replaced ISO 18562-1 with the normative reference YY/T 1778:1-2021 to adapt to the technical conditions of our country;

--- Replaced IEC 62366-1 with the normative referenced YY/T 1474-2006 to adapt to the technical conditions of our country;

--- Replaced IEC 60601-1-6 with the normative referenced YY/T 9706:106 to adapt to the technical conditions of our country;

--- Replaced IEC 60601-1-2:2014 with the normative reference YY 9706:102-2021 to adapt to the technical conditions of our country;

--- Replaced IEC 60601-1-8 with the normative reference YY 9706:108-2021 to adapt to the technical conditions of our country;

--- Replaced IEC 60601-1-11 with the normative reference YY 9706:111-2021 to adapt to the technical conditions of our country;

--- Replaced ISO 80601-2-72:2015 with the normative reference YY 9706:272 to adapt to the technical conditions of our country;

--- Replaced ISO 80601-2-74:2017 with the normative reference YY 9706:274-2022 to adapt to the technical conditions of our country;

--- Added normative reference to ISO 7000 to adapt to the technical conditions of our country: The following editorial changes were made to this document:

--- In the source part of:201:3:201, modify the reference without the date number to the reference with the date code, and change the referenced specific clauses Amended from:201:3:210 to:201:3:205;

---Corrected the error of quoting GB/T 3767-2016 article number in:201:9:6:2:1:101, and included ISO 80601-2-79:2018b) 8:1 in

i) is changed to 8:6, and 8:1 in

l) is changed to 8:2;

--- Modify the article number and content of 202;

--- Corrected the error of quoting the article number in 202:6:2:1:3*, and changed:201:9:6:2:1:101 of ISO 80601-2-79:2018 to 201:12:1:101 or:201:12:1:102;

--- Deleted the terminology index of ISO 80601-2-79:2018;

---Appendix D amended the symbol 5 on the graphics and description of PHT substances: Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the State Drug Administration: This document is under the jurisdiction of the National Anesthesia and Respiratory Equipment Standardization Technical Committee

(SAC/TC116):

Introduction

This document specifies specific requirements for respiratory support equipment intended to be used in a home care environment where the life support of the patient being cared for Not dependent on ventilator ventilation: Such respiratory support equipment is often used in places where the power source is unreliable: Such respiratory support equipment Usually administered by non-medical personnel (inexperienced operators) with varying degrees of training: Respiratory support equipment conforming to this document may also be used Other settings (i:e: healthcare facilities): The development of the respiratory equipment industry in the world tends to be classified more and more finely: According to the degree of patients' symptoms and application scenarios, different categories are distinguished: Home ventilators with the same function can serve different patients more accurately: Specifically, for chronic respiratory failure, such as moderate to mild COPD The patients themselves have a certain ability to move, and the treatment pressure is not great; other patients, such as patients with acute respiratory failure such as severe COPD, also have ALS patients with gradual freezing, the treatment pressure is relatively high, and they need to be transferred to professional medical institutions when they go outdoors to expand their range of activities or during acute attacks: At any time, a ventilator with stronger functional performance is required: Therefore, ISO 10651-6:2004 (YY 0600:1-2007, MOD), when revised Divided into two standards, ISO 80601-2-79:2018 and ISO 80601-2-80:2018: Patients with a steady need for ventilation often require respiratory support: This document applies to patients with significant respiratory dysfunction leading to spontaneous Obvious anomalies that have been noticed: This best distinction is when lung function measures are no worse than: FEV1/FVC (also known as Tiffeneau-Pineli index) < 70%; or 50%<=FEV1< 80% predicted value: Among them, FEV1 is the forced expiratory volume in one second, and FVC is the forced vital capacity: Diseases that require respiratory support such as the above:

---mild to moderate chronic obstructive pulmonary disease (COPD);

--- Neuromuscular/amyotrophic lateral sclerosis (ALS);

---Obesity hypoventilation (OHS);

---Chen Shi's respiration (CSR/CSA): CSR/CSA is an abnormal breathing pattern that usually begins with rapid and deep breathing, followed by slowing down until the breath pauses: stop: This breathing pattern is repeated continuously, and each cycle can be 30s~2min: Cardiac patients with CSR/CSA may feel out of breath without severe reduction in FEV1: can be reduced by The breathing effort helps them get a normal breath: The respiratory support device is intended for spontaneous breathing and does not require life support or intermittent ventilation to maintain vital signs of patients: Respiratory support equipment used for such patients usually does not require a physiological alarm state and therefore has no essential performance: these patients Patients using respiratory support