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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

医用电气设备 第2-69部分：氧气浓缩器的基本安全和基本性能专用要求

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Foreword

This document was issued on 9 March 2021 by the National Medical Products Administration and takes effect on 1 May 2023.

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

It is classified under Chinese classification C46.

All technical content of this part is mandatory. This section was drafted in accordance with the rules given in GB/T 1.1-2009. "Medical Electrical Equipment" is divided into two parts.

---Part 1: General and parallel requirements;

---Part 2: Special requirements. This part is part 2-69. This part replaces YY 0732-2009 "Safety Requirements for Medical Oxygen Concentrators". Compared with YY 0732-2009, except for editorial revisions The technical changes are as follows.

---The original standard is only a safety requirement. This section identifies the basic performance of the oxygen concentrator and its accessories (hereinafter referred to as ME equipment);

---Added requirements related to parallel standards. This part uses the redrafting law to amend and adopt ISO 80601-2-69.2014 "Medical Electrical Equipment Part 2-69: Oxygen Concentrator Specific requirements for basic safety and basic performance. The technical differences between this part and ISO 80601-2-69.2014 and the reasons are as follows.

---Regarding normative reference documents, this section has made adjustments with technical differences to adapt to my country's technical conditions and adjustments. The situation is collectively reflected in the chapter "Normative Reference Documents", and the specific adjustments are as follows. * Added reference to GB/T 4999 (see.201.2); * Replace IEC 60601-1.2012 (see.201.1) with GB 9706.1-2020 which is modified to adopt international standards; * Replace ISO 7010.2011 (see.201.7.5) with GB/T 31523.1-2015 which is modified to adopt international standards; * Replace the international standard IEC 60601-1-2.2007 with YY 9706.102 which is equivalent to the international standard (see.201.1.4); * Replace IEC 60601-1-8.2006 (see.201.1.4) with YY 9706.108 which is modified to adopt international standards; * Replace IEC 60601-1-11.2010 (see.201.2) with YY 9706.111 which is modified to adopt international standards; * Replace IEC 60601-1-6.2010 (see.201.2) with YY/T 9706.106 which is modified to adopt international standards; * Replace the international standard ISO /DIS14644-1.2010 with the international standard ISO 14644-1.2015; * Added reference to ISO 7396-1 (see.201.3); * Added reference to GB/T 3785.1-2010. This section also made the following editorial changes.

---Corrected an error in.201.7.2.13.101 and changed "5.45" to "5.4.5";

---Corrected an error in.201.7.2.17.101 and changed "5.35" to "5.4.5";

---Corrected an error in.201.11.2.101a), and changed the last sentence "Go to step

e)" to "Go to step

---Because of the normative reference documents, the international standard IEC 60601-1-11 is replaced by the modified YY 9706.111 which adopts the international standard. In 2010, the article number "211.4.2.2" was changed to "211.4.2.3";

---Corrected an error in Table.201: C.102, and changed "201.5.101.2" to "201.5.101.1";

---Because IEC 60601-1-11.2010 is no longer quoted in the "definition and term index", the source of the term "wearable" is changed to GB 9706.1-2020. Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This part was proposed by the State Drug Administration. This part is under the jurisdiction of the National Anesthesia and Respiratory Equipment Standardization Technical Committee (SAC/TC116). Drafting organizations of this section. Shandong Shangjian Medical Technology Co., Ltd., Shanghai Medical Device Testing Institute. The main drafters of this section. Ma Yanyan, Xu Chang, Wang Wei, Yu Hongyi. The previous releases of the standards replaced by this part are as follows.

---YY 0732-2009.

Introduction

Oxygen supplementation can be used as part of the management of patients with chronic, acute to chronic, and acute respiratory disorders. The supplemental oxygen content depends on Based on the needs of each patient in different conditions. The health management team usually pre-determines the endpoint of treatment, for example, the target value of oxygen saturation. The amount of supplemental oxygen can be controlled by the flow rate. The purpose of long-term oxygen therapy is to keep the oxygen saturation of patients who need supplemental oxygen greater than 90%. The flow should correspond to rest, exercise and sleep Sleep is adjusted separately to meet the needs of individual patients under these different conditions. Ideally, the oxygen flow is adjusted to the patient's resting The state can maintain the pulse oximeter indicating SpO2 >90%. Supplemental oxygen can be provided by different oxygen sources. medical gas pipeline system, oxygen concentrator, oxygen cylinder and liquid oxygen. Headquarters The specific requirements for the basic safety and basic performance of the oxygen concentrator are sub-specified. Oxygen concentrator produces oxygen-enriched air from ambient air for delivery For patients who need oxygen therapy. The most common oxygen concentrator uses a molecular sieve bed to screen and filter oxygen from ambient air to produce oxygen. The gas concentration is generally 82% to 96%. The main component of this type of oxygen concentrator is molecular sieve, which can adsorb nitrogen from the air Gas, to produce

gas, typically a mixture of 95% oxygen and 5% other gases. The periodic adsorption and discharge of nitrogen is called pressure swing adsorption. Attached process. Medical electrical equipment-Part 2-69: Oxygen concentrator Special requirements for basic safety and basic performance 201.1 Scope, purpose and related standards In addition to the following, Chapter 1 of GB 9706.1-2020 is applicable. 201.1.1 Scope The 1.1 of GB 9706.1-2020 is replaced with. This part specifies the special requirements for the basic safety and basic performance of oxygen concentrators and their accessories. The concentration of gas oxygen delivered to a single patient. This type of oxygen concentrator is usually used in home care environments, including in any private transportation, public transportation It can be operated by a single patient when transferred to an environment including a commercial aircraft.

Note 1: This type of oxygen concentrator can also be used in professional health care institutions. This section applies to oxygen concentrators that can be operated during transfer and those that can be operated during non-transfer. This section applies to integration with or with other medical An oxygen concentrator used with medical equipment, ME equipment or ME systems. Example 1: Oxygen concentrator with oxygen saving device [10] or humidifier [3]. Example 2: Oxygen concentrator used with a separate flow meter. Example 3: An oxygen concentrator used in an anesthesia system [6] used in an area with limited power and logistics supply of anesthetic gas. Example 4: Oxygen concentrator with liquid oxygen tank or gas cylinder filling system. This section also applies to those who are expected to be connected to the oxygen concentrator, and its characteristics affect the basic safety and basic performance of the oxygen concentrator Attachments. This section does not specify the requirements for oxygen concentrators used in medical gas piping systems, see YY 1468 for their requirements. If a chapter or article only applies to ME equipment, or only to ME systems, the title and content of the chapter or article will explain. Otherwise, this chapter or this article applies to related ME equipment and ME systems at the same time. In addition to 7.2.13 and 8.4.1 of the general standard, the expected physiological effects of the ME equipment or ME system within the scope of this part are caused by There are no specific requirements for hazards in this section.

Note 2: Refer to 4.2 of the general standard This part is a special standard of GB 9706.1-2020. 201.1.2 Purpose The 1.2 of GB 9706.1-2020 is replaced with. The purpose of this section is to specify the basic safety and basic performance specific requirements for oxygen concentrators [see definition in.201.3.203] and its accessories. Note. The accessories are included in the standard range, because it is necessary to ensure that the oxygen concentrator and accessories are fully safe when used together. The attachment may be for the oxygen concentrator Basic safety and basic performance have an important impact. 201.1.3 Parallel standards 1.3 of GB 9706.1-2020 applies, adding. This section refers to Chapter 2 of the General Standards and applicable parallel standards listed in.201.2 of this section. GB 9706.103 is not applicable. 201.1.4 Specific standards 1.4 of GB 9706.1-2020 is replaced by the following.