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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Particular requirements for medical respiratory humidifiers and respiratory humidifying systems

医用呼吸道湿化器 呼吸湿化系统的专用要求

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Foreword

This standard is equivalent to ISO 8185..2007 "Special Requirements for Respiratory Humidification Systems for Medical Respiratory Humidifiers" (English version). The main differences between this standard and ISO 8185..2007 are as follows:

--- The IEC and ISO international standards cited in ISO 8185..2007 have been converted into national standards and industry standards. China standards are cited as normative use; if there is no corresponding translation into national standards and industry standards, the cited IEC And ISO international standards are used as norms.

--- ISO 7396-1..2002 "Medical Gas Piping System Part

1 Medical Compressed Gas and Vacuum Piping" has been adopted internationally ISO 7396-1..2007 replaces, so this standard directly references ISO 7396-1..2007.

--- The original standard of this standard

14.6 was "B-type, BF-type and CF-type equipment". According to the adjusted definition of GB 9706.1-2007, Changed to "B-type, BF-type and CF-type application part". Chapter 36 of this standard is compatible with YY 0505-2005 "Medical Electrical Equipment-Part 1-2. General Safety Requirements" Standard. Electromagnetic Compatibility Requirements and Tests "implemented simultaneously. Appendix BB, Appendix DD, Appendix EE, and Appendix FF of this standard are normative appendixes, Appendix AA, Appendix CC, Appendix GG, Appendix HH and Appendix II are informative appendices. This standard was proposed and managed by the National Technical Committee for Standardization of Anesthesia and Respiratory Equipment (SAC/TC116). This standard was drafted. Beijing Yi'an Medical System Co., Ltd. The main drafters of this standard. Kou Liqiang and Li Yunfei. YY 0786-2010/ISO 8185..2007

This standard is a special standard based on GB 9706.1-2007 "Medical Electrical Equipment Part 1. General Safety Requirements", GB 9706.1- 2007 is referred to herein as the "common standard." Common standards are all medical devices used or monitored by qualified personnel in general medical and patient settings The basic standard for electrical equipment safety, it also includes some requirements for reliable operation to ensure safety. Common and side-by-side standards Combined with proprietary standards. The collateral standard includes requirements for specialized technology and/or hazards, and applies to all applications, such as medical systems System, EMC, radiation protection for diagnostic X-ray equipment, software, etc. Specific standards apply to specialized equipment types, such as medical electron accelerators, Frequency surgical equipment, hospital beds, etc.

Note. For the explanation of the parallel standard and the special standard, please refer to

1.5 of the first part of GB 9706.1-2007 and Chapter A.2 of Appendix A, respectively. This standard is consistent with the structure of ISO 8185.Therefore, the numbering of individual chapters, chapters, and articles is different from the general standard. The chapters are consistent with the general standards, and the specific differences are shown in the following table. Chapter This Standard General Standard (GB 9706.1-2007)

1 Scope

YY 0786 is the mandatory Chinese standard for medical respiratory humidifiers and humidifying systems, the equipment that warms and moistens the gas delivered to a patient whose upper airway has been bypassed by a tracheal tube or whose flow rate is too high to be conditioned naturally. Dry gas thickens secretions, blocks tubes and damages the airway lining; excessive heat burns it. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering the temperature and humidity delivered at the patient connection, the control and its failure behaviour, the alarms and the management of condensate. It is the predecessor in scope to YY 9706.274-2022 and remains in force. Compliance is compulsory in China.

In addition to the following, Chapter 1 of GB 9706.1-2007 applies. Modifications (added at

the end of 1.1). This standard specifies the basic safety and basic performance requirements of humidification systems (see definition in 3.6). It also includes special features used in humidification systems. Specific independent devices, such as breathing tube heating (breathing tube heating wire) and control devices for breathing tube heating (breathing tube heating control)

Note. The breathing circuit heating device belongs to medical electrical equipment and should comply with the regulations in GB 9706.1. * This standard also includes the requirements for active HME (heat and humidity exchanger), which is to improve the delivery of HME to patients by actively heating and humidifying Device for the humidity level of a gas. This standard does not apply to passive HMEs, that is, a portion of the moisture and heat that is exhaled by the patient during the inspiration phase A device that returns to the breathing circuit without adding moisture and heat. YY/T 0735.1 and YY/T 0735.2 specify passive HMEs The safety and performance requirements are described, and the methods of performance testing are described. The breathing circuit humidifier can be pneumatic, electric or a combination of both. However, this standard is based on GB 9706.1 A special standard that takes into account all the general requirements for safety, not just electrical safety, but also non-electric but applicable Due to many requirements of the humidifier. This standard specifies that the application of a clause in GB 9706.1 means that it is only applied when the requirements related to the humidification system Consider the application of this clause. This standard does not apply to those devices commonly referred to as "indoor humidifiers" or for humidification of heating, ventilation and air conditioning systems. Not suitable for humidifiers that have been integrated into the incubator. This standard does not apply to atomizing devices that deliver drugs to patients. When planning and designing a product in accordance with this standard, consideration should be given to the environmental impact of the product throughout its life cycle. About Ring Please refer to Appendix GG for environmental impact.

Note. Please refer to YY 0316 for additional information on environmental impact.

2 Normative references

The clauses in the following documents have become the clauses of this standard after being referenced. For dated references, all subsequent documents The amendments (excluding the content of errata) or revisions are not applicable to this section. For undated references, the latest version (package Including any modifications) apply to this standard.

GB/T 3767-1996 Acoustics Engineering method for measuring sound power level of noise source by approximating free field by sound pressure method (eqv, ISO 3744..1994)

GB/T 4999-2003 Anesthesia breathing equipment term (ISO 4135..2001, IDT)

GB/T 5332-2007 Test method for ignition temperature of flammable liquids and gases (ISO 60079-4. 1975, IDT)