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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0671.2-2011

Sleep apnoea breathing therapy - Part 2: Masks and application accessories

睡眠呼吸暂停治疗 第2部分：面罩和应用附件

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Foreword

YY 0671 Sleep Apnea Treatment is divided into two parts.

--- Part 1. Sleep apnea treatment equipment;

--- Part 2. Masks and application accessories. This part is Part 2 of YY 0671. This section is drafted in accordance with the rules given in GB/T 1.1-2009. This part is equivalent to adopting the international standard ISO 17510-2..2007 "Sleep apnea treatment part 2. masks and application accessories" (English Text version). Compared with ISO 17510-2..2007, this section has the following editorial changes.

--- The introduction of ISO 17510-2..2007 is transformed into the introduction of this part;

--- The ISO international standards cited in ISO 17510-2..2007, which have been adopted as national standards and industry standards, this section Use these national standards and industry standards as normative use; if there is no corresponding adoption as national standards and industry standards, Use quoted ISO international standards as norms;

--- Appendix CC in ISO 17510-2..2007 that refers to ISO 17510-1..2007 is directly cited in Appendix K of this section. The original appendix K in the section has been postponed to appendix L. Please note that some elements of this document may involve patents. The issuer of this document is not responsible for identifying these patents. This part is proposed and managed by the National Technical Committee for Standardization of Anesthesia and Respiratory Equipment (SAC/TC116). This section was drafted. Beijing Aerospace Changfeng Co., Ltd., Beijing Yihe Jiaye Medical Technology Co., Ltd., Shanghai

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Sleep apnea is a clinically significant intermittent loss of normal breathing during sleep. In recent years, with the The awareness of the risk of stopping has increased significantly, and the use of sleep apnea treatment equipment has become more and more common. This section covers the use of equipment Requirements for protecting patients' basic safety and primary performance. YY 0671 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 used or monitored by qualified personnel in the usual medical and patient environment The basic standard of medical electrical equipment safety, it also includes some requirements for reliable operation to ensure safety. Common standards are used in combination with side-by-side and proprietary standards. Tiered standards include requirements for special technologies and/or hazards and apply All application equipment, such as medical electrical systems, EMC, radiation protection for diagnostic X-ray equipment, software, etc. Special standards apply to special equipment Types, such as medical electron accelerators, high-frequency surgical equipment, hospital beds, etc.

Note. For the explanation of the parallel standard and the special standard, see

1.5 and A.2. In GB 9706.1-2007, respectively. The clauses marked with an asterisk (*) in this section are described in Appendix A. YY 0671.2-2011/ISO 17510-2..2007 Sleep apnea treatment Part 2. Masks and application accessories

1 Scope

YY 0671.2 covers the masks and accessories used in sleep apnoea therapy, the interface between a CPAP machine and the patient's face. The mask is where the therapy usually fails: a leak drops the pressure that holds the airway open, pressure on the bridge of the nose causes ulceration, and discomfort leads a patient to abandon treatment altogether, which is the commonest reason CPAP does not work. This standard sets the requirements such masks and accessories have to meet and the test methods that verify them, covering the fit and seal, the leak characteristics, the carbon dioxide washout that prevents rebreathing, the biocompatibility of the skin-contacting materials and the connections. Compliance is compulsory in China.

This part of YY 0671 applies to the mask and its attachments and accessories used to connect sleep apnea treatment equipment to the patient. Detailed Detail requirements for masks and accessories, covering components for any necessary connections, including both sleep apnea treatment The patient interface of the device and the parts needed to connect with the patient, including the parts used during sleep apnea treatment, such as nasal masks, drainage Gas port and headband. For requirements on sleep apnea treatment equipment, see Part 1 of YY 0671. Typical of the two parts of the YY 0671 standard For

parts, see Figure A.1. This section does not include requirements for oral appliances.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 3767-1996 Acoustic sound pressure method for measuring sound power levels of noise sources near the free field engineering method (ISO 3744..1994, eqv)

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

GB 9706.1-2007 Medical electrical equipment Part 1. General requirements for safety (

IEC 60601-1. 1988 Amd1..1991 Amd2..1995, IDT)

GB 9706.15-2008 Medical electrical equipment. Part 1-1. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems. Seeking (

IEC 60601-1-1..2000, IDT)

GB/T 14574 Identification and verification of noise emission values of acoustic machines and equipment (GB/T 14574-2000, ISO 4871..1996, eqv)

GB/T 16886 (all parts) Biological evaluation of medical devices (all parts of

ISO 10993) GB/T.19974 Characteristics of sterilization factor of medical care products and setting, confirmation and routine control of sterilization process of medical devices General Requirements (ISO 14937, IDT)

YY/T 0316-2008 Application of medical device risk management in medical devices (ISO 14971..2007, IDT)

YY/T 0466.1-2009 Medical devices. Symbols used for labeling, marking and providing information of medical devices. Part 1. General requirements Seeking (ISO 15223-1..2007, IDT)

YY 0671.1-2009 Sleep apnea treatment part 1. Sleep apnea treatment equipment (ISO 17510-1..2002, MOD)

YY/T 0753.1-2009 Respiratory filters for anesthesia and breathing. Part 1. Salt test method for evaluating filtration characteristics (ISO 23328-1..2003, IDT)

3 Terms and definitions

For the purpose of this standard, GB 9706.1-2007, GB 9706.15-2008, GB/T 4999-2003, YY 0671.1-2009, The terms and definitions defined in ISO 17664..2004, YY/T 0753.2-2009 and the following apply to this document.

Note. For the sake of convenience, this standard gives a list of the source of all the terms defined in alphabetical order in Appendix L.

3.1 Anti-asphyxia valve The on-off valve used in the nasal mask, when the sleep apnea treatment device cannot provide sufficient pressure on the mask end, the valve opens to connect with the atmosphere When the sleep apnea treatment device can provide sufficient pressure at the end of the mask, the valve closes and disconnects from the atmosphere.

3.2 Exhaust flow Airflow to the atmosphere from a mask or application accessory, excluding leaks due to improperly sealed faces.

Note 1. Exhaust flow can pass through openings in the mask, connecting parts and masks, or through anti-asphyxia valves to the atmosphere.

Note 2. Exhaust flow releases exhaled air to the atmosphere to reduce CO2 rebreathing.

3.3 Headgear This section is used to secure the mask to the patient.

3.4 Mask This section is used to connect the patient and patient interface.

Note. According to the application of masks, masks can be divided into. nasal masks, masks and oronasal masks.

3.5 Multi-patientre-use Can be used multiple times by multiple patients.

3.6 Oral appliance oralappliance A device that maintains the airway of the mouth by mechanical means, which can work independently of sleep apnea treatment equipment. 3.7 * Patient connection port Connect the breathing air circuit to the interface of the mask.

3.8 Single-patientreuse Can be used multiple times by the same patient.

4 Information provided by the manufacturer

Note. Appendix H includes a guide to help readers find the identification and labeling requirements contained in other clauses of this part of YY 0671. YY 0671.2-2011/ISO 17510-2..2007

4.1 The label on the packaging, the identification on the mask or accessories, and/or the accompanying documents shall contain the following information.

a) The name (or trademark) and address of the manufacturer and the name and address of the manufacturer or importer's authorized representative or responsible person.

b) Characteristics and use of the mask and all application accessories.

c) * Pressure flow curve of exhaust gas flow in the working pressure range specified in Appendix B.

d) Rated pressure range of the mask (including all parts).