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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 1881-2023

Medical positive pressure air-supply respirator

医用正压送风式呼吸器

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020 "Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents". Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights. This document was proposed by National Medical Products Administration. This document shall be under the jurisdiction of Technical Organization responsible for Standardization of Medical Biological Protection Products. Powered air-purifying respirator (PAPR) used in healthcare settings

1 Scope

YY 1881 is the mandatory Chinese standard for the powered air-supply respirator used in healthcare, the unit that draws air through a filter and delivers it under positive pressure to a hood or facepiece. Unlike a filtering facepiece it does not rely on a seal against the wearer's face, which is what makes it usable by staff with beards or awkward facial geometry and

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comfortable enough to wear for a long shift. The document sets the requirements such a respirator has to meet and the test methods that verify them, covering the filtration efficiency, the airflow delivered, the battery endurance, the noise and the alarms that warn of a failing supply. Being a YY standard without the /T suffix, compliance is compulsory in China. It took effect in July 2025, alongside the positive pressure suit standard YY 1887.

This document specifies the classification and tags, requirements, test methods, marks and instructions for use, packaging and storage of powered air-purifying respirator used in healthcare settings. The document is applicable to powered air-purifying respiratory protection devices that are working in medical working environment or other environment where the risk of exposure to pathogenic microorganism aerosols is assessed, used to filter microbial particles in the air and block pollutants such as droplets and blood. This document does not apply to powered air-purifying respirator for protection against toxic and hazardous gases. It is also not suitable for respirators for industrial dust, combustion, explosion, oxygen-deficient environments and escape.

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2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2410-2008, Determination of the luminous transmittance and haze of transparent plastics

GB 2626-2019, Respiratory protection -- Non-powered air-purifying particle respirator

GB/T 3785.1-2010, Electroacoustics -- Sound level meters -- Part

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 powered air-purifying respirator; PAPR A filter-type respiratory protective equipment that relies on a powered flow rate system (3.3) to provide airflow to overcome component resistance.

3.5 loose-fitting respirator with respiratory interfaces covering the head A partially tight powered air-purifying respirator (3.1) that covers the entire head to the neck.

3.6 tight-fitting respirator with respiratory interfaces covering the head A powered air-purifying respirator (3.1) that covers the entire head to the neck and has a close-fitting design at the neck.

3.7 air exhaust port A component that is installed on the hood (mask) and exhausts the air inside it.

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4 Classification and tags

The powered air-purifying respirator used in healthcare settings specified in this document consists of at least a powered flow rate system, a filter element, an air supply tube, and a hood (or mask).

5 Requirements

5.1 Basic requirements Product materials and structural design shall meet the following requirements.

5.2 Primary skin irritation For materials that come into direct contact with the head, face or neck, skin irritation shall be evaluated in accordance with GB/T 16886.10.The primary skin irritation index shall not be greater than 0.4.

5.3 Filter element

5.4.2 If the flow rate is monitored and displayed in real time, the indication error shall not exceed ±5%.

5.5 Continuous use time Under the maximum flow rate conditions designed by the manufacturer, the continuous use time shall not be less than 4 h.

5.6 Anti-crushing of air supply tube When a pressure of 50N is applied, the flow rate of the respirator shall not drop by more than 5%. After the pressure is removed for 5 min, the air supply tube shall not be deformed.

5.7 Prompt function

5.7.1 Prompt for low flow rate The product shall have a low flow rate prompt function and meet the following requirements.

5.7.2 Prompt for low battery The product shall have a low battery prompt function and meet the following requirements.

5.8 Total inward leakage The total inward leakage under each action shall meet the requirements of Table 2.

5.24 Electrical safety and electromagnetic compatibility

5.24.1 Electrical safety shall comply with the requirements of GB 9706.1.

5.24.2 Electromagnetic compatibility shall comply with the requirements of YY 9706.102.

6 Test methods

6.1 Test conditions Unless otherwise specified, the test shall be carried out in an

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environment with a temperature of 16°C~32°C and a relative humidity of (50±30)%.

6.5 Environment test The environment test of the powered flow rate system is carried out in accordance with the climate environment group II and mechanical environment group II in GB/T 14710- 2009, see Table 5.

6.6 Pretreatment conditions According to the storage conditions claimed by the manufacturer, place it at the lowest temperature and lowest humidity for (72±1) h. Then place it at normal room temperature for at least 4 h.

6.7.2 Mechanical strength Take at least 4 filter elements and perform mechanical strength pretreatment on the filter elements according to the method in

6.2.2 of GB 2626-2019.

6.7.3 Filtration efficiency

6.7.3.3 Testing methods Carry out the loading test under the minimum flow rate conditions specified in 5.4.1. The total aerosol loading shall be at least (200 ± 5) mg.

6.8.3 Test methods Before testing, make sure the battery is fully charged. You can run the fan for a while until the flow rate is lower than the minimum flow rate requirement, and then charge the battery according to the manufacturer's recommendations.

6.12 Total inward leakage

6.12.1 Sample preparation At least 2 sets of respirator samples shall be pre-conditioned according to the requirements of 6.6.

6.12.2 Test methods The subjects shall wear the respirator correctly. The tight-fitting respirator shall ensure the edges are close-fitting. Adjust to the lowest flow rate level. Test the total inward leakage according to the method specified in YY/T 0866 (except for the pretreatment method). The head sampling pipeline layout is shown in Figure 3.

7.1 Marks

7.1.1 Hood (face mask) The hood (face mask) product shall at least contain the category mark (cL, dL or dT). Reusable hoods (face masks) shall be able to ensure that the category mark is clearly identifiable after the maximum number of disinfections according to the disinfection method specified by the manufacturer. The smallest package shall have clear Chinese marks, including at least the following information.

7.1.3 Filter elements The smallest package shall have clear Chinese marks, including at least the following information.

7.2 Instructions for use The instructions for use shall contain at least the following information.

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