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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 19083-2023

Replacing GB 19083-2010

Protective face masks for medical use

医用防护口罩

Issued on: November 27, 2023 **Implemented on: December 1, 2025**

Issued by: State Administration for Market Regulation;
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1 Scope

China's mandatory standard for medical protective face masks - the respirator worn by healthcare workers against infectious aerosols, and the companion of GB 19082 which covers the protective coverall. It specifies the requirements, the marking, the instructions for use and the packaging and storage of disposable medical protective face masks, and describes the corresponding test methods. What makes a respirator different from a surgical mask is the direction of protection: a surgical mask stops what the wearer emits, a respirator stops what the wearer would otherwise breathe in, and that requires two things at once. The filter medium must remove the particles, which the standard sets as a filtration efficiency measured against a defined aerosol at a defined flow. And the mask must seal to the face, because air takes the easiest path and a gap at the nose or the cheek carries unfiltered air straight past a filter of any efficiency - which is why the standard sets the total inward leakage and the requirements on the nose clip, the headbands and their attachment strength, and why a respirator has to be fit tested on the individual wearer rather than simply issued. To those are added the breathing resistance, which decides whether the mask can be worn for a shift and is the property that is traded against filtration; the resistance to penetration by synthetic blood, since this mask is worn where blood may be splashed; the flame retardance; the skin irritation and biological requirements; and the sterility where the mask is supplied sterile. The marking and instructions must state the level of protection and the correct donning, seal check and disposal. Issued on 27 November 2023 and in force since 1 December 2025, it replaces GB 19083-2010.

This document specifies the requirements, markings, instructions for use, as well as packaging and storage of disposable protective face mask for medical use (hereinafter referred to as "face mask"), and describes the corresponding test methods. This document is applicable to non-powered air-purifying face masks (half masks) for filtering particles in the air and blocking droplets, blood, body fluids, secretions, etc. in medical working environments. This document does not apply to masks that protect against any chemical gases and vapors.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the version corresponding to that date is applicable to this document; for undated references, the latest version (including all amendments) is applicable to this document.

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

GB/T 14233.1-2022, Test methods for infusion, transfusion, injection equipment for medical use - Part

3 Terms and definitions

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

3.1 filtering efficiency The percentage of particulate matter filtered out by the mask under specified test conditions.

3.2 dead space The volume of air that is re-inhaled from the previous exhalation.

Note. It is expressed by the volume fraction of CO2 in the inhaled gas. [Source: GB/T 12903-2008, 5.3.10]

3.3 total inward leakage; TIL The ratio of the concentration of the simulated agent leaking into the mask from all parts including the mask when the subject inhales TO the concentration of the simulated agent in the test environment under the test conditions specified in the laboratory. [Source: GB/T 12903-2008, 5.3.7, modified]

3.4 fit The degree of fit between the periphery of the mask and the specific user's face.

4 Requirements

4.1 Basic requirements Mask materials and structural design shall meet the following requirements.

a) The appearance of the mask is free from damage and stains;

b) The mask can cover the wearer's mouth and nose and fit tightly to the face;

c) The mask shall not be equipped with an exhalation valve;

d) The mask is equipped with a nose clip or a design as an alternative of the nose clip, which can be used for fixing and tightening when worn;

e) The mask belt is made of elastic material or adjustable design, which is easy to wear and remove, and can firmly fix the mask on the face.

4.2 Mask belt connection strength

4.2.1 The breaking strength of each mask belt shall not be less than 10 N.

4.2.2 The breaking strength at each connection point between the mask belt and the mask body shall not be less than 10 N.

4.3 Filtration efficiency Under the specified test flow conditions, the filtering efficiency of the mask for non- oily particles shall meet the requirements in Table 1.

4.4 Respiratory resistance The inspiratory resistance and expiratory resistance of the mask shall meet the requirements in Table 1.

4.5 Dead space The average volume fraction of CO2 in inhaled air shall not exceed 1%.

4.6 Total inward leakage The total inward leakage shall meet the requirements in Table 1.

4.7 Resistance against penetration by synthetic blood Spray 2 mL of synthetic blood onto the mask at a pressure of 16 kPa (120 mmHg), and there shall be no penetration on the inside of the mask.

4.8 Microbiological indicators

4.8.1 Sterile masks shall be sterile.

4.8.2 The total number of microorganisms in non-sterile masks shall be less than or equal to 100 CFU/g.

4.9 Ethylene oxide residue (if applicable) If the mask has been ethylene oxide-sterilized or disinfected, its ethylene oxide residue shall not exceed 10 μg/g.

4.10 Flammability (if applicable) If the manufacturer expressly states that the mask material is not flammable, when testing according to 5.12, the after-flame time shall not exceed 5 seconds.

4.11 Biocompatibility

4.11.1 Skin irritation The primary stimulation score shall not be greater than 0.4.

4.11.2 Cytotoxicity The relative cell proliferation rate (survival rate) shall not be less than 70%.

4.11.3 Delayed type hypersensitivity Delayed type hypersensitivity shall not be greater than grade 1.

5 Test methods

5.1 Test conditions Except for special requirements, the test shall be carried out in an environment with a temperature of 16 °C ~ 32 °C and a relative humidity of (50±30)%.

5.2 Basic requirements Randomly select at least 3 masks from 3 minimum independent packaging units, visually inspect and actually wear them, and check whether they meet the requirements of 4.1.

5.3 Temperature and humidity pretreatment conditions Remove the sample packaging and perform pretreatment in the following order.

a) Place in an environment of (38±2.5) °C and (85±5)% relative humidity for (24±1) h;

b) Place in a dry environment of (70±3) °C for (24±1) h;

c) Place in an environment of (-30±3) °C for (24±1) h. The pretreatment method used should avoid thermal shock, and allow the sample temperature to return to room temperature for at least 4 hours before subsequent pretreatment or testing.