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Translated by: www.ChineseStandard.net
Wayne Zheng et al.
Email: Sales@ChineseStandard.net

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NATIONAL STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

GB 19083-2010

Replacing GB 19083-2003

Technical Requirements for Protective Face Mask for Medical Use

医用防护口罩技术要求

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中华人民共和国国家标准

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1 Scope

This Standard specifies the technical requirements, test methods, markings and instructions for use, packaging, transportation and storage for protective face mask for medical use (hereinafter referred as mask).

This Standard is applicable to non-powered air-purifying medical protective face mask - used in medical service environments to filter particulate matters in air and to separate spray, blood, body fluid, secretion, etc.

2 Normative References

Those provisions contained in following documents, through quotation of this Standard, constitute the provisions of this Standard. For dated document, subsequent amendments (excluding the corrections) or revisions of the document do not apply. However, parties who have signed agreement based on these standards are encouraged to investigate the possibility of adopting the most recent editions of the standards indicated below (subsequent amendments or revisions). For any undated documents, the latest edition of the document

3 Terms and Definitions

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

3.1

Filtering efficiency

The percentage number of filtering particulate matters in air under specified conditions

3.2

Fit

The degree of mask periphery fitting to the face of a specific user

3.3

Fit factor

The ratio of the testing agent's concentration outside the mask to the testing agent's concentration leaking into the mask, which is quantitatively measured during the testees wearing masks for simulating actions, process and operation

4 Technical Requirements

4.1 Basic requirement of mask

The mask shall cover the wearer's nose and mouth and shall be of a good facial fit and without broken holes, stain or expiratory valve.

4.2 Nasal splint

4.2.1 The mask shall have a nasal splint.

4.2.2 The nasal splint shall be adjustable.

4.3 Mask harness

4.3.1 The mask's harness shall be adjustable conveniently.

4.3.2 The mask's harness shall be of sufficient strength to fix the mask. The breaking strength of the junction between each mask harness and the mask body shall not be less than 10N.

4.4 Filtering efficiency

With the gas flow at 85L/min, the filtering efficiency of mask to non-oily particles shall

The primary irritation scoring of the mask materials shall not exceed 1.

4.12 Fit

The mask shall be so designed to provide a good fit and the overall fit factor of the mask shall not be less than 100.

5 Test Methods

5.1 Basic requirement of mask

Take 3 masks and observe at 300 lx~700 lx. They shall meet the requirement of 4.1.

5.2 Nasal splint

It shall be adjusted as specified in the instructions and shall comply with 4.2.

5.3 Mask harness

5.3.1 Sample quantity: take and unpack 4 masks – two of them shall undergo temperature pretreatment; and the other two do not undergo temperature pretreatment.

5.3.2 Condition for temperature pretreatment:

Pretreatment condition:

a) Keep in 70℃±3℃ environment test chamber for 24h;

b) Keep in-30℃±3℃ environment test chamber for 24h.

After temperature pretreatment, keep at room temperature for at least 4h.

5.3.3 The result of visual inspection and the result measured by tension test device shall meet the requirement of 4.3.

5.4 Filtering efficiency and gas flow resistance test

5.4.1 Sample quantity: take 6 mask samples for the test. Three of them shall undergo temperature pretreatment and the other three do not undergo temperature pretreatment.

5.4.2 Condition for temperature pretreatment:

Pretreatment condition:

a) Keep in 70℃±3℃ environment test chamber for 24h;

b) Keep in-30℃±3℃ environment test chamber for 24h.

After temperature pretreatment, keep at room temperature for at least 4h.

5.4.3 The gas flow shall be stabilized 85L/min±2L/min.

The distribution of particle size of sodium chloride (NaCl) aerosol used under the specified test condition shall be such that the count median diameter (CMD) is 0.075μm±0.020μm, geometric standard deviation does not exceed 1.86 (equivalent to 0.24μm±0.06μm in mass median aerodynamics diameter (MMAD)), and concentration does not exceed 200 mg/m^3.

5.4.3.1 The determination results of filtering efficiency shall meet all the requirements of 4.4.

5.4.3.2 The determination results of inspiration resistance shall meet all the requirements of 4.5.

5.5 Synthetic blood penetration

5.5.1 Sample quantity: 5 mask samples shall be taken for the test.

5.5.2 Pretreatment condition: the mask samples shall undergo pretreatment for at least 4h in an environment test chamber at 21℃±5℃ in temperature and 85%±5% in relative humidity. The test shall be carried out within 1min after the mask samples' withdrawal from the chamber.

5.5.3 As the test is carried out in accordance with the test method in YY/T 0691-2008, the result shall meet those provisions specified in 4.6. See Appendix A for the preparation of synthetic blood.

5.6 Surface wetting resistance test

Three masks shall be taken for the test. As the test is carried out by reference to the method specified in GB/T 4745-1997, the result shall meet the requirement of 4.7.

5.7 Microorganism index

5.7.1 As the test is carried out in accordance with the method specified in Appendix B of GB 15979-2002, the result shall meet the requirement of 4.8.1.

5.7.2 Masks marked as sterilized and aseptic shall undergo the test in accordance with the method specified in GB/T 14233.2-2005 and the result shall meet the requirement of 4.8.2.

5.8 Oxirane residue

5.8.1 Gas chromatograph condition

The gas chromatograph shall meet the following conditions:

a) Hydrogen flame detector: not less than 2×10-11g/s in sensitivity [benzene, carbon bisulfide (CS_2)].

d) Product registration number;

e) Filter material grade or description;

f) Letters or symbols indicating "Refer to Instructions for Use before Use";

g) Storage conditions and guarantee period;

h) Letters indicating "Disposable" or equivalent shall be marked on disposable products;

i) The sterilization validity period and sterilization mode shall be indicated on sterilized products.

6.1.2 Marking on packing container:

The packing container shall be provided at least with the following details or marks:

a) Name and address of manufacturer or supplier;

b) Product name and model;

c) Reference to standard;

d) Product registration number;

e) Specification and quantity;

f) Production date or batch number;

g) Lettering and marking like Sun Protection and Keep Dry (the marking shall meet those specified in GB/T 191);

h) Storage conditions and validity period.

6.2 Instructions for use

The instructions for use shall be at least in Chinese and shall provide the following details:

a) Application and service restrictions;

b) Denotation of product color code (if applicable);

c) Inspection required before use;

d) Wear fitness;

e) Usage;

f) Storage conditions;

g) Implication of symbol and (or) diagram applied;

h) Possible problems and cautions;

Appendix A (Informative)

Preparation of Synthetic Blood

A.1 Reagents

Prepare 1L synthetic blood according to the following composition:

Carboxymethyl cellulose sodium [e.g., CMC-Sigma 9004-32-4 medium viscosity]	2g
Polyoxyethylene (20) sorbitan monolaurate {e.g., Tween-20[Fluka 9377]}	0.04g
Sodium chloride (analytical grade)	2.4g
Amaranth dye [e.g., Sigma 915-67-3](915-67-3)	1.0g
Monopotassium phosphate (KH_2PO_4)	1.2g
Disodium hydrogen phosphate ($Na_2 HPO_4$)	4.3g
Distilled water or deionized water	To 1L

Note 1: 2-Methyl-4-isothiazolin-3-one hydrochloride (MIT) (0.5 g/L) may be added in the synthetic blood to extend the storage period of the solution.

Note 2: Sigma 9004-32-4, Fluka 9377, Sigma 915-67-3 and Fluka 9377 are examples for applicable commercial products. This information allows for the user of this Standard but not represents the recognition of those products.

A.2 Preparation

Make carboxymethyl cellulose sodium dissolved in 0.5 L water and make them mixed completely with a magnetic stirrer for 60min.

Use a small beaker to weigh Tween 20 and make it completely mixed with water.

Add the Tween 20 solution in the carboxymethyl cellulose sodium solution. The beaker shall be cleaned with distilled water for several times and the water used shall be incorporated in the former solution.

Make NaCl dissolved in the solution. Make KH_2PO_4 and Na_2HPO_4 dissolved in the solution.

Add MIT (if applied) and amaranth dye.

Dilute the solution with water to approximately 1000mL.

Regulate the synthetic blood to pH 7.3 ± 0.1 and scale to 1000mL with phosphate buffer.

Appendix B (Normative)

Fitness Test Method

B.1 Test environment

The test space size shall allow for the testee to perform specified testing actions freely. The number of particles in air shall not be less than 70×106 particles/m^3If the number of particles is too small, an aerosol generator may be adopted to increase the particles in environment and as for the particles from the aerosol generator, the count median diameter (CMD) is about 0.04μm and geometric standard deviation is about 2.2 (equivalent to 0.26μm in mass median aerodynamics diameter (MMAD)). If sodium chloride aerosol is used, the relative humidity of air shall not be greater than 50%.

B.2 Installing mask sampling tube

Puncture at the location "respiratory area", near to the wearer's mouth and nose, to install a sampling tube. The sampling tube shall be mounted on the neck support device of testee to reduce the interference to the mask in the test process.

B.3 Test procedure

Select 10 testees with men and women in fifty-fifty percent respectively. Their headforms shall be in compliance with the Chinese headform series of GB/T 2428-1998. For male, their beard shall be shaved. Wear the mask according to the instructions for use. Before testing, inspection for moving of mask, over-looseness or over-tightness of mask harness, fitness of nasal splint for nose bridge and leakage from mask periphery shall be carried out. No readjustment is allowed in the test process. The testees are required to perform the following 6 actions, each of which shall last for 1min:

a) Normal respiration——keep standing, normal respiration speed and speechless.

b) Deep breathing ——keep standing, take a deep breath gradually, do not exhale excessively.

c) Turning left and right——keep standing, turn head to one side until to the extreme position and then turn to the other side. At each extreme position, inspiration shall be

performed.

d) Turning up and down——head down slowly and then up slowly. At the upper extreme position, inspiration shall be performed.

e) Speaking ——speak loudly and slowly. Ask the testees to count down from 100 or read an article.

f) Normal respiration ——see a).

B.4 Calculating fit factor

B.4.1 The fit factor of each action is calculated from the ratio of the mean concentration of particles outside the mask to that inside the mask, which is determined through calculation.

B.4.2 The mean concentration of particles outside the mask may adopt the arithmetic mean of the before-and after-test (6 actions) concentrations or the mean concentration before and after each action, or the actual mean of continuous measurement.

B.4.3 The concentration of particles inside the mask shall be calculated as follows:

a) Mean peak penetration method: use recorder, integrator or computer to determine the number of particles that passed through the mask. In each action, work out the mean peak height from the recording paper or integrate with computer to determine the number of particles. Selectively, use an integrator or computer to work out the actual number of particles that passed through the mask.

b) Maximum peak penetration method: use banding recorder to determine the number of particles that pass through the mask. The peak of each required action represents the mean number of particles that passed through the mask for the action.

c) Area integration method: integrate the area of the peak of each action. It includes computer integration.

d) Overall fit factor calculation: convert the fit factors of each action to penetration values and work out their mean which is then reconverted to fit factor, as detailed in Formula (B.1).

$$FF = \frac{6}{1/ff_a + 1/ff_b + 1/ff_c + 1/ff_d + 1/ff_e + 1/ff_f} \qquad \text{(B.1)}$$

Where:

FF——the overall fit factor;