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# National Standard of the People's Republic of China

GB 19083-2010
Replace GB 19083-2003

# Technical requirements for protective face mask for medical use

## 医用防护口罩技术要求

*（English Translation）*

（报批稿）

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# Foreword

Beijing Institute of Medical Device Testing is in charge of this English translation. In case of any doubt about the contents of English translation, the Chinese original shall be considered authoritative.

This standard is mandatory except clause 4.10 as voluntary.

This standard replaces the GB 19083-2003 *Technical requirements for protective face mask for medical use*.

This standard compared to the previous edition (GB 19083-2003), the main changes are as follows:

—Modified the applicable “Scope ”of the standard;

—Supplemented and revised the “Normative references ” ;

—Added and editorially modified the Terms and definitions;

—Deleted the requirement for mask size;

—Deleted the requirement for noseclip length;

—Added the requirement and test method for “fit”;

—Revised requirement for “skin irritation” according to GB/T 16886.10-2005, clarified the test method;

—Deleted the technical requirements for marking and user’s manual;

—test method of ethylene oxide residuals is replaced to gas chromatography method in GB/T 14233.1-2008 from GB 15980-1995;

—Modified the test method for microbial index.

Annex B of this Standard is normative. Annex A is informative.

This standard is proposed by China Food and Drug Administration.

This standard is prepared by SAC/TC 136 (Standardization Technical Committee of Clinical Laboratory Testing and *In vitro* Diagnostic Test Systems).

The previous edition of this Standard is as follows:

—GB 19083-2003

# Technical requirements for protective face mask for medical use

## 1 Scope

This standard specifies the technical requirements, test methods, marking and instructions for use, packaging and storage for medical protective face masks (hereinafter referred to as mask).

This standard is applicable for non-powered air-purifying medical protective face mask which can filter airborne particles and block droplets, blood, body fluids, secretions, etc. under medical work settings.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments (excluding corrections), or revisions, of any of these publications do not apply to this standard. However parties to agreements based on this standard are encouraged to investigate the possibility of applying the recent editions of the normative references indicated below. For undated references, the latest edition of normative document referred to applies.

GB/T191, *Packaging- Pictorial marking for handling of goods*

GB/T 2428-1998, *Head-face dimensions of adults*

GB/T 4745-1997, *Textile fabrics-Determination of resistance to surface wetting-Spray test*

GB/T 5549-1990, *Surface active agents-Determination of surface tension by drawing up liquid films*

GB/T 14233.1-2008, *Test methods for infusion, transfusion, injection equipments for medical use - Part 1: Chemical analysis methods*

GB/T 14233.2-2005, *Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods*

GB 15979-2002, *Hygienic standard for disposable sanitary products*

GB/T 16886.10-2005, *Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity*（ISO 10993-10:2002, IDT）

GB/T 18664-2002, *Selection, use and maintenance of respiratory protective equipment*

YY/T 0691-2008, *Clothing for protection against infectious agents—Medical face masks—Test method for resistance against penetration by synthetic blood(fixed volume, horizontally projected)*（ISO 22609:2004, IDT）

YY/T 0700-2008, *Clothing for protection against contact with blood and body fluids—Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood*（ISO 16603:2004,IDT）

## 3 Terms and definitions

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

**3.1**

**filter efficiency**

The percentage that the mask filters the airborne particles at specified conditions.

**3.2**

**fit**

The degree that the mask seals around wearer’s face.

**3.3**

**fit factor**

The ratio measured quantitatively between the concentration of test agent outside the mask and the concentration of test agent that have leaked into the mask, while the wearer simulating work activities.

## 4 Technical requirements

### 4.1 General requirements for masks

The mask shall cover the wearer's nose and mouth, with good fit to the face. It shall not have broken holes or stains on the surface of the mask. The mask shall not have exhalation valve.

### 4.2 Noseclip

4.2.1 The mask shall be mounted with noseclip.

4.2.2 The noseclip shall be adjustable.

### 4.3 Head harness

4.3.1 The Head harness shall be easy to be adjusted.

4.3.2 The harness should provide adequate tension to hold the mask in position. Breaking force at the

connection point between each mask strap and mask body shall not be less than 10N.

### 4.4 Filter efficiency

At air flow rate of 85 L/min, the filter efficiency of the mask for non-oil particles shall comply with the requirements of Table 1.

**Table1 Classification of filter efficiency**

| Classification | Filter efficiency,% |
|---|---|
| Level 1 | ≥95 |
| Level 2 | ≥99 |
| Level 3 | ≥99.97 |

### 4.5 Breathing resistance

At air flow rate of 85 L/min, the inhalation resistance of the mask shall not exceed 343.2 Pa (35 mm $H_2O$)

### 4.6 Synthetic blood penetration

Synthetic blood of 2mL sprayed onto the mask sample at the pressure of 10.7 kPa (80 mmHg), the inside of the mask shall not be penetrated.

### 4.7 Resistance to surface wetting

The spray rating of outer surface of mask shall not be lower than the description of Level 3 in GB/T4745-1997.

### 4.8 Microbial index

4.8.1 The mask shall meet the requirements of microbial index in the GB 15979-2002, as shown in Table 2.

4.8.2 Masks marked "Sterilize" or "Sterile" on the packaging shall be sterile.

**Table 2 Microbial Index of Mask**

| Total bacterial colonies CFU/g | Coliform bacteria | *Pseudomonas aeruginosa* | *Staphylococcus aureus* | *Hemolytic streptococcus* | Total fungal colonies CFU/g |
|---|---|---|---|---|---|
| ≤200 | Not detected | Not detected | Not detected | Not detected | ≤100 |

### 4.9 Residual quantity of ethylene oxide

For mask sterilized by ethylene oxide, the residual quantity of ethylene oxide shall not exceed 10 μg/g.

### 4.10 Flame retardant property

The material used shall not be flammable. Afterflame time shall not exceed 5s.

### 4.11 Skin irritation

The primary irritation score of the mask materials shall not be greater than 1.

### 4.12 Fit

The mask shall be designed to fit well, the overall fit factor of the mask shall not be less than 100.

## 5 Test methods

### 5.1 General requirements for masks

Take 3 mask samples and carry out visual inspection under illumination of 300 lx-700 lx, the results shall meet the requirements of 4.1.

### 5.2 Noseclip

Adjustments shall be made in accordance with instructions for use and meet the requirements of 4.2.

### 5.3 Head harness

5.3.1 Sample quantity: A total of 4 masks are used, removed from the packaging, and 2 are subjected to temperature preconditioning and 2 as received.

5.3.2 Temperature preconditioning:

Treatment conditions are as follows:

a) For 24h in a 70°C±3°C environmental test chamber;

b) For 24h in a -30°C±3°C environmental test chamber.

Samples shall be restored for at least 4h at the room temperature after temperature preconditioning.

5.3.3 Tested by visual inspection and measurement through tensile test equipment, the results shall meet the requirements of 4.3.

### 5.4 Filter efficiency and Breathing resistance test

5.4.1 Sample quantity: 6 mask samples shall be used for test. 3 are subjected to temperature preconditioning, and 3 as received.

5.4.2 Temperature preconditioning:

Treatment conditions are as follows:

a) For 24h in a 70°C±3°C environmental test chamber;

b) For 24h in a -30℃±3℃ environmental test chamber.

Samples shall be restored for at least 4h at the room temperature after temperature preconditioning.

5.4.3 The air flow rate should be stabilized to 85 L/min±2 L/min.

At the specified test condition, the sodium chloride (NaCl) test aerosol shall have a particle size distribution with count median diameter (CMD) of 0.075 μm±0.020 μm, and a geometric standard deviation not exceeding 1.86 (equivalent to mass median aerodynamic diameter (MMAD) of 0.24μm±0.06μm). The concentration should not exceed 200 mg/m$^3$.

5.4.3.1 All the results of filter efficiency test shall meet the requirements of 4.4.

5.4.3.2 All the results of inhalation resistance test shall meet the requirements of 4.5.

**5.5 Synthetic blood penetration**

5.5. 1 Sample quantity: 5 mask samples shall be used for test.

5.5.2 Pretreatment conditions: The mask samples are subjected to preconditioning at temperature of 21℃±5℃ and relative humidity of 85%±5% in an environmental test chamber for at least 4h. The mask samples shall be tested within 1min after taking out of the environmental chamber.

5.5.3 Carry out the test by the method specified in YY/T 0691-2008, and the results shall meet the requirements of 4. 6. For synthetic blood preparation method, see Annex A.

**5.6 Resistance to surface wetting test**

A total of 3 masks shall be tested by the method specified in GB/T 4745-1997, and the results shall meet the requirements of 4.7.

**5.7 Microbial index**

5.7.1 The test shall be carried out in accordance with the methods specified in Annex B of the GB 15979-2002, and the results shall meet the requirements of 4.8.1;

5.7.2 The masks marked with "Sterilized" or "Sterile" shall be tested according to the method specified in GB/T 14233. 2-2005, and the results shall meet the requirements of 4. 8.2.

**5.8 Residual quantity of ethylene oxide**

5.8.1 Requirements for gas chromatography

The gas chromatography shall meet the following conditions:

a) Hydrogen flame ionization detector: Sensitivity better than $2\times10^{-11}$g/s [Benzene, carbon disulfide

($CS_2$)];

b) Chromatographic column: The chromatographic column used shall separate ethylene oxide from impurities in the test sample completely, and have a certain degree of water resistance. For chromatographic column, recommended conditions in Table 3 can be used.

**Table 3 Recommended conditions for chromatographic columns**

| Column length | Internal diameter | Support | Column oven temperature |
|---|---|---|---|
| 1m-2m | 2mm-3mm | GDX-407 177μm~147μm( 80 mesh~100 mesh) | About 130℃ |
| | | Porapak q-s 177 μm~147 μm( 80 mesh~100 mesh) | About 120℃ |

c) Temperature of each part of the instrument

Vaporizing chamber: 200℃;

Detector chamber: 250℃.

d) Gas flow rate

$N_2$:15 mL/min-30 mL/min;

$H_2$:30 mL/min;

Air: 300 mL/min.

5.8.2 Test procedures

Two specimen are tested with the exhaustive extraction method using water as extraction medium as specified in GB/T 14233.1—2008, 9.4, and the results are obtained with the relative content method as specified in GB/T 14233.1—2008, 9.5.2. The arithmetic mean value is calculated unless there is unqualified number which shall be measured again.

The result shall meet the requirements of 4.9.

**5.9 Flame retardant property**

5.9.1 Sample quantity: 4 mask samples shall be tested. 2 are subjected to temperature preconditioning, and 2 are as received.

5.9.2 Temperature preconditioning:

Treatment conditions are as follows:

a) For 24h in the air at 70℃±3℃;

b) For 24h in the air at -30℃±3℃.

Samples shall be restored for at least 4h at the room temperature after temperature preconditioning.

5.9.3 Procedures:

5.9.3.1 Mount the mask on the metal head dummy, and the distance from the top of burner to the lowest

part of the mask (when placed directly facing the burner) shall be set at 20mm± 2mm.

5.9.3.2 Adjust the flame height to 40mm±4mm. Using a mineral insulated thermocouple probe, the flame temperature measured 20mm±2mm above the top of burner, shall be 800℃±50℃.

5.9.3.3 Make the head dummy passing through the flame at the linear speed of 60mm/s±5mm/s and record the combustion state of the mask after passing through the flame one time. The result shall meet the requirements of 4.10.

### 5.10 Skin irritation

Tested according to the primary skin irritation method specified in GB/T 16886.10-2005, the results shall meet the requirements of 4.11 of the Standard.

### 5.11 Fit test

Choose 10 test subjects wearing masks in accordance with the instructions for use to complete six prescribed exercises, test in accordance with the method specified in Annex B. The overall fit factors of at least 8 subjects shall meet the requirements.

## 6 Marking and Instructions for Use

### 6.1 Marking

6.1.1 Marking for smallest package of mask

The smallest package of the mask shall have at least the following clear and legible markings. If the package is transparent, the markings shall be legible through the packaging:

a) Name and model of the products;

b) Name of the manufacturer or supplier;

c) Applicable standard number;

d) Product registration number;

e) Filter classification or related description;

f) The sentence or symbols of "Please refer to the instructions before use";

g) Storage conditions and expiry date;

h) Disposable product shall be marked with "Disposable" or equivalent;

i) For a sterilized product, sterilization validity and sterilization method shall be indicated.

6.1.2 Package mark

The package shall have at least the following contents or marks:

a) Name and address of manufacture or supplier;

b) Name and model of products;

c) Applicable standard number;

d) Product registration number;

e) Specification and quantity;

f) Production date or batch number;

g) Words and symbols of “Keep away from sunlight”, “Keep dry” etc. Symbols should comply with GB/T191;

h) Storage conditions and shelf life.

### 6.2 Instructions for use

Instructions for use shall be in Chinese at least. The instructions should give at least the following information:

a) Intend use and use restrictions;

b) Meaning of color code (if applicable);

c) Inspections to be performed before use;

d) Wearing fit;

e) Use methods;

f) Storage conditions;

g) Meaning of the symbols and/or diagrams used;

h) Problems likely to be encountered and precautions;

i) Recommended time for use;

j) Applicable standard number;

k) Product registration number.

## 7 Packaging and storage

### 7.1 Packaging

7.1.1The package of mask shall be able to prevent mechanical damage and contamination before use.

7.1.2 The masks shall be packaged in claimed quantity.

### 7.2 Storage

Store as specified in the instructions for use.

# Annex A
(informative)
# Synthetic blood preparation method

### A.1 Ingredients

The following formula can be used to prepare 1L of synthetic blood:

| | |
|---|---|
| sodium carboxymethyl cellulose (e.g. CMC-Sigma 9004-32-4 medium viscosity) | 2 g |
| polyoxyethylene(20) sorbitan monolaurate {e.g. Tween 20[Fluka 9377 ] } | 0.04 g |
| sodium chloride (analytical purity) | 2.4 g |
| amaranth dye (e.g. Sigma 915-67-3) | 1.0 g |
| potassium dihydrogen phosphate（$KH_2PO4$） | 1.2 g |
| disodium hydrogen phosphate ($Na_2HPO_4$） | 4.3 g |
| distilled or deionized water | up to 1 L |

Note1: 2-Methyl-4-isothiazolin-3-one hydrochloride(MIT)(0.5 g/L) can be added to increase the storage lifetime of the solution.

Note2: Sigma 9004-32-4, Fluka 9377 and Sigma 915-67-3 are examples of suitable commercial products. The information is given here just for the convenient use of this standard. It does not present the recognition of these products.

### A.2 Preparation methods

Dissolve sodium carboxymethyl cellulose in approximate 0.5 L water and mixed on a magnetic stirrer for 60 min.

Weigh the Tween 20 in a small beaker, add water and mix well.

Add the Tween 20 solution to sodium the carboxymethyl cellulose solution, and rinse the beaker several times with distilled water and add this to the former solution.

Dissolve sodium chloride in the solution. Then dissolve $KH_2PO_4$ and $Na_2HPO_4$ into the solution.

Add MIT（if used）and amaranth dye.

Dilute the solution with water to nearly 1,000mL.

Adjust the pH of the synthetic blood to 7.3±0.1 with phosphate buffer solution, and set the volume to 1,000mL.

Measure the surface tension of the synthetic blood according to GB/T 5549-1990. The result should be 0.042 N/m±0.002 N/m.

# Annex B
(normative)
# Fit test method

**B.1 Test environment**

The size of test room should allow the test subjects to complete the specified exercise freely. The number of particles in the air should not be less than $70\times10^6/m^3$. If the number of particles is too low, an aerosol generator can be used to increase the particles in the environment. Particles generated by the aerosol generator shall have a particle size distribution with count median diameter (CMD) of 0.04μm approximately, and a geometric standard deviation about 2.2. In case of sodium chloride aerosol used, the relative humidity of the air shall not be greater than 50%.

**B.2 Install mask sampling tube**

Puncture the "breathing area" of the mask near wearer's mouth and nose, and install sampling tubes. The sampling tube should be fixed on a supporting device worn by the subject around the neck to minimize interference to the mask during the test.

**B.3 Test procedures**

Choose 10 test subjects, including five male and five female, head-face dimensions of the test subjects shall be in the range of that defined in GB/T 2428-1998. The males shall have their beard shaved. Wear the face mask following the instructions for use. Prior to the test, check the following: no moving tendency of the mask, the mask strap not too loose or too tight, noseclip fit across nose bridge, no leakage around the mask edge, etc. No adjustment is allowed during the test. The subjects are required to complete the following 6 prescribed exercises, each exercise lasting 1min.

a) Normal breathing - standing position, normal breathing rate, no talking.

b) Deep breathing – standing position, breathe slowly and deeply, taking caution so as not to hyperventilate.

c) Turning head side to side - standing position, slowly turn the head to one side until the extreme position and then to the other side, and inhale at each extreme position.

d) Moving head up and down - Head down slowly, and then head up slowly, and inhale at the extreme position of head up.

e) Talking – talk slowly and loudly. Have the subject countdown from 100 or read an article.

f) Normal breathing – same as a).

**B.4 Calculation of fit factor**

B.4.1 Calculate the fit factor of each exercise by calculating the ratio of the measured average

concentrations of particles outside and inside the face mask.

B.4.2 The average concentration of particles outside the mask can be the arithmetic mean of concentrations before and after test (6 exercises) or the mean value of concentrations before and after each exercise or the real mean value of continuous measurement.

B.4.3 Concentration inside the mask is calculated by one of the following methods:

a) Average peak penetration method: Use a strip recorder, integrator or computer to determine the number of particles that have entered the mask. For each exercise, determine the number of particles by calculating the average peak height on the recording paper or by computer integration. Integrator or computer may also be used to calculate the actual number of particles that have actually entered the mask.

b) Maximum peak penetration method: Use a strip recorder to determine the number of particles that have entered the mask. The peak of particles during each given exercise represents average number of particles that have entered the mask during the exercise.

c) Area integration method: Carry out integral calculation of the area under the peak during each exercise. Computer integration is included.

d) Calculation of overall fit factor: Convert the fit factor of each exercise to the penetration value, calculate the mean value, and then convert the results back into the fit factor. See formula (B.1).

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

where：

FF —Overall Fit factor

$ff_a$ —Fit factor of normal breathing ;

$ff_b$ —Fit factor of deep breathing;

$ff_c$ —Fit factor of turning head side to side;

$ff_d$ —Fit factor of moving head up and down;

$ff_e$ — Fit factor of talking;

$ff_f$ —Fit factor of normal breathing.