GB 19083 - 2010

Technical requirements for medical protective face masks

Publish by
AQSIQ: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China
CNSC: China National Standardization Administration Committee

Foreword

4.10 of this standard is the recommended requirement and the rest is mandatory.
Appendix B of this standard is the normative appendix and Appendix A is the informative appendix.
This standard is proposed by the State Food and Drug Administration.
This standard is centralized by the National Technical Committee for Standardization of In Vitro Diagnostic System for Medical Clinical Laboratory.

Technical requirements for medical protective masks

1 Scope

This standard provides for medical protective masks (hereinafter referred to as masks) technical requirements, test methods, signs and instructions for use and packaging, transport and storage.
This standard is applicable to the medical work environment, filtering the particulate matter in the air, barrier droplets, blood, body fluids, secretions and other self-absorption filter type medical protective masks.

2 Normative references

The provisions in the following documents become the provisions of this standard by reference to this standard. All subsequent revisions (excluding errata) or revisions of dated references shall not apply to this standard, however, parties agreeing to this standard are encouraged to explore the possibility of using the latest version of these documents. The latest version of an undated reference document applies to this standard.

GB/T 191: packaging, storage and shipping diagrams
GB/T 2428-1998: head and face size of adult
GB/T 4745-1997: surface moisture resistance of textile fabrics, water contamination test
GB/T 5549-1990: surfactant, determination of surface tension by pull-up liquid film method
GB/T 14233.1-2008: Test methods for medical infusions, blood transfusions, syringes devices, Part 1: Chemical analysis methods
GB/T 14233.2-2005: Test methods for medical infusion, blood transfusion and syringe devices,

Part 2: Biological test methods
GB 15979-2002: Hygiene standards for disposable sanitary products
GB/T 16886.10-2005: Biological evaluation of medical devices, Part 10: Hypersensitivity test for stimulation and delayed hairstyle
GB/T 18664-2002: Selection, use and maintenance of respiratory protection
YY/T 0691-2008: Anti-synthetic blood penetration test method (fixed volume, horizontal injection) for protective equipment against infectious agents, medical masks
YY/T 0700-2008: Anti-blood and body fluid penetration testing, synthetic blood test methods, for blood and body fluid protective equipment, protective clothing materials

3 Terms and definitions

The following terms and definitions apply to this standard.

3.1 Filtering efficiency
Percentage of particulate matter filtered out of the air by the mask under specified conditions.

3.2 Fit
The degree of closeness of the mask perimeter to the specific user's face.

3.3 Fit factor
Quantitative measurement of the ratio of the concentration of test agent on the outside of the mask to the concentration leaking into the inside in the course of a simulated operational activity in which a person wears a mask.

4 Technical requirements

4.1 Basic requirements for masks
The mask should cover the wearer's mouth and nose, there should be a good facial fit, the surface should not have holes, stains, there should be no expiratory valve.

4.2 Nose clip
The mask should be fitted with a nose clip, which should be adjustable.

4.3 Earbands for masks
The earbands for mask should be easily adjustable. There should be sufficient strength to hold the mask in place. The fracture strength of each earband at the point of connection with the mask body shall be not less than 10N.

4.4 Filtration efficiency
At a gas flow rate of 85 L/min, the mask's filtration efficiency against non-oily particles should meet the requirements of Table 1.

Table 1: Filtration efficiency classes

Class	Filtration Efficiency %
Class 1	≥95
Class 2	≥99
Class 3	≥99.97

4.5 Airflow resistance

At a gas flow rate of 85 L/min, the suction resistance of the mask must not exceed 343.2 Pa (35 mm H_2O).

4.6 Synthetic blood penetration

Spray 2mL of synthetic blood at 10.7kPa (80mm Hg) into the mask, which should not show penetration when measured inside the mask.

4.7 Surface moisture resistance

The level of moisture resistance on the outer surface of the mask shall be not less than the class 3 specified in GB/T 4745 - 1997.

4.8 Microbiological indicators

The mask shall meet the requirements of the microbiological indicators in GB 15979 - 2002, see Table 2. Masks with sterile markings on the packaging shall be sterile.

Table 2 Microbiological indicators for masks

Total bacterial colonies CFU/g	Escherichia coli	Pseudomonas aeruginosa
≤200	must not be detected	must not be detected
Staphylococcus aureus	hemolytic streptococcus	Total fungal colonies CFU/g
must not be detected	must not be detected	≤100

4.9 Ethylene oxide residues

Ethylene oxide sterilized masks with an ethylene oxide residue of not more than 10 μg/g.

4.10 Flame retardant properties

The material used should not be flammable. Continued ignition time should not exceed 5s

4.11 Skin irritation

The primary stimulus score for the mask material should not exceed 1

4.12 Conformity

The mask should be designed to provide a good fit with a total fit factor of the mask should not be less than 100

5 Test method

5.1 Basic requirements for masks

Three masks are taken and visually examined at 300lx ~ 700lx illumination, which should meet

the 4.1 requirement.

5.2 Nose clamp
Adjustment according to the method of use specified in the instructions shall comply with the requirements of 4.2.

5.3 Earbands for masks

5.3.1 Sample number:
4 masks, opened and packaged, 2 with temperature pretreatment and 2 without pretreatment.

5.3.2 Temperature pretreatment conditions
Pretreatment conditions are: 24H in a 70℃ ± 3℃ ambient chamber, 24H in a -30℃ ± 3℃ ambient chamber, after temperature pretreatment should be restored at room temperature to at least 4H.

5.3.3 The results shall meet the requirements of 4.3, as measured by visual inspection and tensile testing devices.

5.4 Filtration efficiency and airflow resistance tests

5.4.1 Sample number: 6 mask samples should be used for testing, 3 are temperature pretreated and 3 are not pretreated.

5.4.2 Temperature pretreatment conditions
The pretreatment conditions are: 24H in a 70℃ ± 3℃ ambient chamber, 24H in a -30℃ ± 3℃ ambient chamber, after temperature pretreatment should be restored at room temperature to at least 4H.

5.4.3 The gas flow should be stabilized to 85L/min ± 2L/min
The size distribution of sodium chloride (NaCl) aerosol particles for the specified test conditions should be a median particle size diameter (CMD) of 0.075 μ m ± 0.020 μ m with a geometric standard deviation of not more than 1.86 (equivalent to a median aerodynamic mass diameter, MMAD, of 0.24 μ m ± 0.06 μ m). Concentrations not exceeding 200 mg/m^3

The filtration efficiency shall be measured in accordance with 4.4 and the suction resistance in accordance with 4.5.

5.5 Synthetic blood penetration

5.5.1 Sample number: 5 mask samples should be used for the test.
5.5.2 Pre-treatment conditions: mask samples were pretreated at least 4H in an ambient chamber at 21℃ ± 5℃, 85% ± 5% relative humidity. Mask samples were removed from the ambient chamber for testing within 1min.

5.5.3 The test shall be conducted in accordance with the test method YY/T 0691 - 2008 and the results shall comply with the provisions of 4.6. See Appendix A for the preparation of synthetic blood.

5.6 Surface moisture resistance test

Three masks were taken and tested in accordance with the methods specified in GB/T 4745-1997, the results of which should all meet the requirements of 4.7.

5.7 Microbiological indicators

5.7.1 The test shall be performed in accordance with the methods specified in Appendix B of GB 15979-2002 and the results shall meet the requirements of 4.8.1.
5.7.2 Masks marked as sterile shall be tested in accordance with the methods specified in GB/T 14233.2 - 2005 and the results shall meet the requirements of 4.8.

5.8 Ethylene oxide residues

5.8.1 Gas chromatograph conditions

Gas chromatograph should meet the following conditions: hydrogen flame detector, sensitivity not less than $2*10^{-11}$g/s. [benzene, carbon disulfide (CS_2)]
Column: The column should be able to separate the impurities and ethylene oxide in the specimen, and have a certain water resistance. The conditions recommended in Table 3 are available for the chromatographic column.

Table 3 Recommended conditions for chromatographic columns

Column Length	Inner Diam	Stretch	Column Temp
1m ~ 2m	2mm ~ 3mm	GDX-407 177 μm~147 μm (80mesh~100mesh)	about 130℃
		Porapak q-s 177 μm~147 μm (80mesh~100mesh)	about 120℃

Temperature of all parts of the instrument
Gasifier: 200℃
Testing room: 250℃
Gas flow rate
N_2: 15mL/min~30mL/min
H_2: 30mL/min
Air: 300mL/min

5.8.2 Testing steps

In accordance with GB/T 14233.1 - 2008 9.4, GB 15980 - 1995, the extreme leaching method specified in appendix G, water as a solvent, parallel tests are carried out in accordance with GB/T

14233.1 - 2008 9.5.2, GB 15980, relative content method specified in appendix G. The results are calculated as an arithmetic average, if one passes and the other fails, the average shall not be calculated and shall be determined again. The results should meet the requirements of 4.9.

5.9 Flame retardant properties

5.9.1 Sample size: Four mask samples shall be tested, two samples temperature pretreated and two samples not pretreated.

5.9.2 Temperature pretreatment conditions

24H in 70℃ ± 3℃ air, 24H in -30℃ ± 3℃ air, and at least 4H at room temperature after pretreatment.

5.9.3 Steps

5.9.3.1 Place the mask on the metal head mold and set the distance between the top of the burner and the lowest part of the mask (when placed directly against the burner) at 20mm ± 2mm.

5.9.3.2 Adjust the flame height to 40mm ± 4mm and measure the flame temperature with a metal-isolated thermocouple probe at 20mm ± 2mm above the burner tip at 800℃ ± 50℃.

5.9.3.3 Pass the head mold through the flame at a line of motion speed of 60mm/s ± 5mm/s and record the burning state of the mouthpiece after passing through the flame once. Results should meet requirement 4.10

5.10 Skin irritation

The test shall be performed in accordance with the primary skin irritation method specified in GB/T 16886.10-2005 and the results shall comply with the provisions of 4.11 of this standard.

5.11 Conformity

Select 10 subjects, wear a mask according to the instruction manual, perform 6 prescribed movements, and test according to the methods specified in Appendix B. At least 8 subjects should meet the total fitness factor requirement.

6 Signs and instructions for use

6.1 Signs

6.1.1 Marking of minimum packaging for masks

The minimum packaging of the mask should have at least the following clear and easily recognizable markings, which should be visible through the packaging if it is transparent.

a) Product name, model
b) The name of the manufacturer or supplier;
c) Executive standard number;
d) Product registration number;
e) Filter media grade or corresponding instructions;
f) The text or symbol "Please refer to the instructions for use before use";
g) Storage conditions and expiry date;
h) Single-use products should be marked with the words "single-use" or equivalent.
i) In the case of sterilized products, indicate the expiration date and the method of sterilization.

6.1.2 Box marking
The box should have at least the following contents or logo on it.

a) The name and address of the manufacturer or supplier
b) Product name, model
c) Implementation standard number
d) Product registration number
e) Number of specifications
f) Date of production or lot number
g) Sun and moisture resistant lettering and signs in accordance with the provisions of GB/T 191.
h) Storage conditions and expiry date

6.2 Instructions for use
Instructions for use should be in Chinese, at least, and should give at least the following

a) Use and use restrictions.
b) The meaning of the product colour code (if applicable).
c) Pre-use inspections.
d) Wearability
e) Method of use
f) Storage conditions
g) Meaning of symbols or diagrams used
h) Questions that may arise and considerations should be given
i) Recommendations on the duration of mask use
j) Implementation standard number
k) Product registration number

7 Packaging and storage

7.1 Packaging: The mask should be packaged to prevent mechanical damage and pre-use contamination. Masks are boxed by quantity.
7.2 Storage: In accordance with the instructions for use.

Appendix A: Synthetic Blood Formulation Methods

A.1 Reagents

Equipped with 1L of synthetic blood according to the following formula:

Sodium carboxymethyl cellulose [e.g., viscosity in CMC-Sigma 9004-32-4]	2g
Polyoxyethylene(20) sorbitan monolaurate (e.g., Twain 20 [Fluka 9377])	0.04g
Sodium chloride (analytically pure)	2.4g
Amaranth red dye [e.g., Sigma 915-67-3] (915-67-3)	1.0g
Potassium dihydrogen phosphate (KH_2PO_4)	1.2g
Disodium hydrogen phosphate (Na_2HPO_4)	4.3g
Distilled water or deionized water	Add to 1L

Note 1: 2-Methyl-4-isothiazolin-3-one hydrochloride, MIT, (0.5g/L) can be added to 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 of suitable commercial products. This information is given for the convenience of users of this standard and does not constitute an endorsement of this product.

A.2 Formulation methods

Dissolve sodium abdominal methylcellulose in 0.5L of water and mixed on a magnetic stirrer for 60min.

In a small beaker, weigh Tween 20 and add water and mix well.

Add the Tween 20 solution to the sodium carboxymethyl cellulose solution and wash the beaker several times with distilled water, then add to the previous solution.

Dissolve the NaCI in solution. Dissolve KH_2PO_4 and Na_2HPO_4 in the solution.

Add MIT (if using) and amaranth red dye.

Dilute the solution by nearly 1000mL with water.

Adjust the pH of the synthetic blood to 7.3 ± 0.1 with phosphate buffer and fixed to 1000mL.

The surface tension of synthetic blood was measured according to GB/T 5549-1990 and the result should be $0.042N/m \pm 0.002N/m$.

Appendix B: Suitability Test Methods

B.1 Test environment

The test space shall be of such size as to allow the subject to freely perform the prescribed test action. The number of particles in the air should be no less than $70*10^6/m^3$. If the number of particles is too small, the aerosol generator can be used to increase the number of particles in the environment, and the aerosol generator produces particles with a median particle diameter (CMD) of approximately 0.04um and a geometric standard deviation of approximately 2.2 (equivalent to a median aerodynamic mass diameter, MMAD, of 0.26um). If sodium chloride aerosols are used, the relative humidity of the air should be no more than 50%.

B.2 Installation of mask sampling tubes

A sampling tube is installed by puncturing the "breathing area" of the mask near the mouth and nose of the wearer. The sampling tube should be secured to a support device worn around the subject's neck to minimize interference with the mouthpiece during the test.

B.3 Test steps

Ten subjects, male and female halves, were selected, with head shapes in line with the GB/T 2428-1998 head shape series. Men shave off their beards. Wear a good mask according to the instructions for use. Before the test, you should carry out a check, including the mask does not have a tendency to move, the mask strap should not be too loose or too tight, the nasal clip should fit the bridge of the nose, the perimeter should not leak air, etc. No further adjustments are allowed while testing is in progress. Subjects were asked to do the following 6 prescribed movements for 1min each

a) Normal breathing: standing position, normal breathing rate, no speech
b) Deep breathing: standing posture, take slow deep breaths, taking care not to hyperventilate.
c) Turning head left and right: in a standing position, slowly turn your head to one side to the limit position and then to the other side, there should be inhalation at each limit position.
d) Moving the head up and down: Slowly lower the head, then slowly raise the head, there should be an inhalation motion at the limit of the head.
e) Speak: Speak loudly and slowly. Have subjects count backwards from 100 or read a passage.
f) Normal breathing, as in a)

B.4 Calculation of the fit factor

B.4.1 The fit factor for each action is calculated by calculating the ratio of the measured average concentration of particles outside the mask to the average concentration inside the mask.
B.4.2 The average concentration of particles outside the mask may be an arithmetic average of the concentrations before and after the test (6 actions), or an average of the concentrations before and after each action, or a true average of the continuous measurements.
B.4.3 The concentration in the mask is calculated by one of the following methods
a) Average peak penetration method: the number of particles entering the mask is determined using a strip recorder, integrator or computer. For each action, the number of particles was determined by calculating the average peak height on the recording paper or by computer integration. It is also possible to calculate the number of particles that actually enter the mask with a calculator or computer
b) Maximum peak penetration method: the number of particles entering the mask is determined using a strip recorder. The highest wasp through which each given action particle passes represents the average amount of entry of that action into the mouthpiece.
c) Area integration method: calculate the area integration under each action peak. Includes computer credits.
d) Calculate the total fit factor: first convert the fit factor for each movement to the penetration

value, calculate the average, and then convert the results back to the fit factor. As in formula (B.1).

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

In the formula.

FF: Total fit factor

ff_a: fit factor for normal breathing

ff_b: Fit factor for deep breathing

ffc: Fit factor for left and right moving head

ffd: fit factor for moving the head up and down

ff_e: the fit factor for talking

ff_f: fit factor for normal breathing