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Protective face mask for medical use

医用防护口罩

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Protective face mask for medical use

1 Scope

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 1: Chemical analysis methods

GB/T 16886.5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

GB/T 16886.10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

GB/T 16886.12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

GB/T 32610-2016, Technical specification of daily protective mask

YY 0469, Surgical mask

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)

YY/T 0866, Total inward leakage determination method of protective face mask for medical use

Pharmacopoeia of the People's Republic of China 2020 Edition Volume IV

ISO 16900-5:2016/Amd.1:2018, Respiratory protective devices - Methods of test and test equipment - Part 5: Breathing machine, metabolic simulator, RPD headforms and torso, tools and verification tools/Amendment 1: RPD head forms front and side view

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.

4.5 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 $16\text{ }^{\circ}\text{C} \sim 32\text{ }^{\circ}\text{C}$ and a relative humidity of $(50\pm 30)\%$.

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 $(38\pm 2.5)\text{ }^{\circ}\text{C}$ and $(85\pm 5)\%$ relative humidity for $(24\pm 1)\text{ h}$;
- b) Place in a dry environment of $(70\pm 3)\text{ }^{\circ}\text{C}$ for $(24\pm 1)\text{ h}$;
- c) Place in an environment of $(-30\pm 3)\text{ }^{\circ}\text{C}$ for $(24\pm 1)\text{ h}$.

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.

5.4 Mask belt connection strength

5.4.1 Number of samples

Take at least 4 mask samples and perform temperature and humidity pretreatment according to 5.3.

5.4.2 Testing methods

Fix the main body of the mask with the outer side of the mask facing up; cut the mask belt from the middle; let the mask belt hang naturally; apply a static pull force of 10 N at the end for 10 seconds. The mask belt and the connection must not be disconnected. In case of disconnection, the disconnection part (mask belt or connection point) shall be reported.

If there is no fixed connection between the mask belt and the mask body, the mask belt shall be removed, with one end fixed, and the other end loaded with a static tension force of 10 N for 10 seconds. The mask belt shall not be disconnected.

Keys:

- | | |
|--|----------------------------|
| 1 – aerosol generator; | 7 – mask; |
| 2 – compressed air source; | 8 – two-way valve; |
| 3 – flow control module; | 9 – aerosol photometer 1; |
| 4 – gas release (when the test flow rate is lower than the spray flow rate); | 10 – aerosol photometer 1; |
| 5 – air supply (when the test flow rate is higher than the spray flow rate); | 11 – flow meter; |
| 6 – testing cabin; | 12 – vacuum pump. |

Figure 1 – Schematic diagram of filtering efficiency testing device

5.5.3 Testing methods

When the detection flow rate is (85 ± 4) L/min, carry out the loading test, and the total loading amount shall be at least (50 ± 5) mg.

Before starting the test, fix and seal the edge of the mask to keep the shape of the mask consistent with the normal wearing mode; if necessary, use a special clamp. After the test starts, record the filtering efficiency during the loading process. When the specified loading capacity is not reached and the filtering efficiency is lower than the grade limit required in 4.3, the test shall be stopped and the sample shall be judged to be unqualified. When the specified loading capacity is reached and the filtering efficiency has not been lower than the required limit of this grade, judge it to be qualified. Record the lowest value during the test as the filtering efficiency of the mask.

5.6 Respiratory resistance

5.6.1 Number of samples

Take at least 4 mask samples and perform temperature and humidity pretreatment according to 5.3.

5.6.2 Testing equipment and testing conditions

5.6.2.1 Test head form

The head form specified in Appendix D of GB 2626-2019, Appendix B of GB/T 32610-2016 or ISO 16900-5:2016/Amd.1:2018 can be used.

5.6.2.2 Testing equipment and conditions

5.9 Resistance against penetration by synthetic blood

Take at least 4 masks and carry out the test according to the method specified in YY/T 0691-2008. If all the results meet the requirements of 4.7, judge it as qualified. For the preparation method of synthetic blood, see YY 0469.

5.10 Microbiological indicators

5.10.1 Sterility

Carry out the test in accordance with the test methods for sterility inspection method (General Chapter 1101) of the *Pharmacopoeia of the People's Republic of China* (2020 Edition, Volume IV). Carry out the treatment of the test sample and the inoculation culture medium in accordance with the provisions of the dressing test sample in the direct inoculation method.

5.10.2 Microbial limits

Carry out the test in accordance with the membrane-filter procedure stipulated in the microbial enumeration method (General Chapter 1105) in the microbial limit inspection of non-sterile products in *Pharmacopoeia of the People's Republic of China* (2020 edition, volume IV). Obtain the total number of microorganisms by adding the results of the total number of aerobic bacteria, mold and yeast.

Preparation of test solution: Randomly select at least 2 smallest packages; take no less than 10 g of the test sample; cut it into pieces and use a diluent containing 0.1% (volume fraction) polysorbate 80 (or other non-bacterial surfactant) – such as pH 7.0 sterile sodium chloride-peptone buffer, or pH 7.2 phosphate buffer, or 0.9% sterile sodium chloride solution – to prepare a 1:50 (g/mL) test solution; mix thoroughly.

5.11 Residue of ethylene oxide

Carry out the test according to the method specified in 9.4 of GB/T 14233.1-2022.

5.12 Flammability

5.12.1 Number of samples

Take at least 4 mask samples and perform temperature and humidity pretreatment according to 5.3.

5.12.2 Testing methods

Follow the following steps for testing. When all samples meet the requirements of 4.10, judge them to be qualified.

- a) Wear the mask on the metal head form, and set the distance between the top of the burner and the lowest part of the mask (when placed directly facing the burner) at (20 ± 2) mm.
- b) Adjust the flame height to (40 ± 4) mm. Use a metal-isolated thermocouple probe to measure the temperature of the flame at (20 ± 2) mm above the top of the burner, which shall be (800 ± 5) °C.
- c) Pass the head form through the flame at a linear speed of (60 ± 5) mm/s, and record the combustion state of the mask after passing through the flame once.

5.13 Biocompatibility

5.13.1 Sample preparation

Mix the mask belt and the mask body materials according to the area ratio of 1:3 as a test sample. Prepare the leach solution of the test sample in accordance with the requirements of GB/T 16886.12.

5.13.2 Skin irritation

Carry out the test according to the primary skin irritation method specified in GB/T 16886.10.

5.13.3 Cytotoxicity

After using complete cell culture medium to dilute the test sample leach solution twice, carry out the cytotoxicity test according to the MTT method in GB/T 16886.5. The relative cell proliferation rate shall not be less than 70%.

5.13.4 Delayed type hypersensitivity

Use the maximum dose for delayed type hypersensitivity in guinea pigs specified in GB/T 16886.10 for the test.

6 Marking and instruction for use

6.1 Marking

The minimum sales unit of masks shall be provided with a clear Chinese marking, which shall at least include:

- a) Product name and grade specified in this document;
- b) Model and specifications;
- c) Production date and/or batch number;

Appendix A

(Informative)

Fit test method before mask selection

A.1 Necessity

The fit of protective face mask for medical use is directly related to the protective effect of the wearer during actual use. Due to differences in individual face shapes, efforts in the design of protective mask products can only improve its fit among different individuals, that is, it can achieve better facial fit in a larger proportion of the population, but it cannot fit all wearers. For protective face masks for medical use of a certain model and size, users need to conduct a fit test before selecting them to reduce the risk of leakage from the fitting part.

A.2 Evaluation cycle

Changes in physical condition may change the fit of a user wearing a protective mask of the same brand, model, and size. Influencing factors may include significant changes in weight, changes in facial fitting parts (such as scars, dental corrections, etc.), and reduction in wearing comfort. Relevant agencies can organize a fit test for protective face masks for medical use once a year, which can also be determined based on the actual situation or other regulations, and can be carried out at any time when necessary.

A.3 Precautions for mask wearers

Mask wearers need to know the product size information and wearing method in advance, check whether the appearance is damaged, etc. and, after wearing, perform air tightness inspection according to the method specified by the manufacturer. Placing a mirror in the test area can better assist the wearer in checking.

The wearer shall choose a mask that makes him/her feel comfortable subjectively when wearing it. Any discomfort, such as the sense of oppression caused by a tight mask belt, may only gradually appear after the wearer wears it for a period of time. Therefore, before the fit test, the wearer shall subjectively feel the mask for at least 5 minutes after correctly wearing it, and the feeling time can be extended if necessary. During the feeling period, the particles remaining in the breathing area during the wearing process can also be self-purified through the breathing process to prevent any impact on the fit test results.

If there is beard hair at the fitting part between the mask and the face, it will also affect the fit test results to varying degrees. Therefore, before the fit test, the wearer needs to shave off the skin of the fitting part, which shall be carried out within 24 hours from the fit test. If conditions permit, it shall be carried out within 12 hours.

A.5.2 Qualitative fit test

A.5.2.1 Principle

This method is a fit test method based on the wearer's subjective feeling of the simulating agent. At present, simulating agents are usually sweetening agents or bittering agents. Qualitatively determine the inward leakage of the protective mask through the wearer's perception of taste. When testing, only one reagent shall be selected, and bittering agents are used more often than sweetening agents. The sweetening agent is generally sodium saccharin solution, and the bittering agent is generally denatonium benzoate solution (Bitrex).

A.5.2.2 Brief introduction to the method

After putting on the mask, the wearer puts the head into a special test hood, and another person sprays sweetening agent or bittering agent aerosol particles into the test hood. If the wearer does not taste sweetness or bitterness when completing each action, the fit test is passed; if the wearer tastes sweetness or bitterness, the test fails, and shall wear the mask again or replace the mask before testing again. The specific test method can be carried out in accordance with the operating procedures of the commercial testing device.

This method relies on the wearer's taste sense to subjectively feel leakage. Therefore, at least 15 minutes before the test, any behavior that may interferes with taste, such as eating, drinking, chewing gum, smoking, etc., needs to be eliminated. Before the test, the wearer must first be screened for taste threshold to prove that he or she can detect aerosol particles of lower concentrations through taste. Wearers who cannot pass the taste threshold screening cannot be tested for fit by the qualitative method based on sweetening agents or bittering agents. After the wearer tastes sweetness or bitterness during taste threshold screening or subsequent testing, it usually takes a period of time to remove the residual taste from the lips and tongue; alternatively, it can be eliminated by rinsing and gargling.

A.5.3 Quantitative fit test

A.5.3.1 Brief introduction

Quantitative fit test is a fit test method that quantifies the concentration of simulating agents inside and outside the mask through a specific testing device, where ambient aerosol condensation nuclei-counting (CNC) is a widely used quantitative method.

A.5.3.2 Principle of CNC method

This method uses particles in the environment as background values. When the wearer puts on the mask and completes prescribed actions, respectively detect the number of aerosol particles in the environment and inside the mask. By calculating the ratio of the

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