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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0969-2023

Single-use medical face mask

一次性使用医用口罩

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020 "Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents". This document replaces YY/T 0969-2013 "Single-use medical face mask". Compared with YY/T 0969-2013, in addition to the structural adjustments and editorial modifications, the main technical changes in this document are as follows:

a) Change the definition for "bacterial filtration efficiency" (see

3.1 of this Edition;

3.1 of Edition 2013);

b) Change the definition for "airflow resistance" (see

3.2 of this Edition;

3.2 of Edition 2013);

c) Change the requirements for "appearance" (see

4.1 of this Edition;

4.1 of Edition 2013);

d) Change the requirements for "structure and dimensions" (see

4.2 of this Edition;

4.2 of Edition 2013);

1 Scope

YY/T 0969 is the Chinese standard for the ordinary single-use medical face mask, the everyday mask worn in clinical settings, as distinct from the surgical mask of YY 0469 and the respirator of GB 19083. It sets the technical requirements such a mask has to meet, the test methods that verify them, and the marking, packaging, transport and storage rules. The properties it governs are the ones that decide whether a mask does its job: filtration efficiency, breathing resistance, the microbiological cleanliness of the product and the skin-contact safety of the materials. It is the document customs, hospital tenders and export contracts refer to when a mask is described as medical, and the text a Chinese registration reviewer applies. The 2023 edition is the current one, in force since December 2025.

This document specifies the technical requirements, test methods, marks, packaging, transportation and storage for single-use medical face mask. This document is applicable to single-use face masks that cover the user's mouth, nose and jaw, and are worn in general medical environments to block exhaled or sprayed pollutants from the oral and nasal cavities. This document does not apply to medical protective masks and medical surgical masks.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 bacterial filtration efficiency; BFE Under specified testing conditions, the mask's ability to filter out bacteria-containing suspended particles. NOTE. It is usually expressed as a percentage.

3.2 airflow resistance The resistance of the mask under the specified area and specified flow rate. NOTE. It is expressed as pressure difference per unit area.

4 Technical requirements

4.1 Appearance The mask shall be clean in appearance and in good shape. There shall be no obvious defects such as damage, stains, sharp protrusions, etc. on the surface.

4.2 Structure and dimensions After the mask is worn, it shall cover the wearer's mouth, nose and chin. It shall comply with the marked dimensions and allowable deviations specified by the manufacturer. The design of the mask shall be able to distinguish its inner and outer sides.

4.3 Nose clip

4.3.1 The mask shall be equipped with a nose clip or a structure that replaces the nose clip.

4.3.2 The structure of the nose clip or nose clip replacement shall be such that the mask can be effectively fixed on the nose and fit well to the nose area. The length of the nose clip shall be no less than 50% of the marked length on the side where the nose clip is located.

4.4 Mask strap

4.4.1 Earhook mask The sum of the breaking strengths of each mask strap and the two connection points between each mask strap and the mask body shall not be less than 15 N.

4.4.2 Strap mask The breaking strength of each mask strap and the connection between each mask strap and the mask body shall be no less than 10 N. If there is no fixed connection point between the mask strap and the mask body, the breaking strength of each mask strap shall be no less than 10 N.

4.5 Bacterial filtration efficiency (BFE) The bacterial filtration efficiency of the mask shall be no less than 95%.

4.6 Airflow resistance The airflow resistance for gas exchange on both sides of the mask shall be less than

4.7 Microbial indicators

4.7.1 Microbiological limits (products supplied in a non-sterilized manner) The total number of microorganisms shall be <=30 CFU/g.

4.7.2 Sterility (products supplied in a sterilized manner) Masks shall undergo a confirmed sterilization process and the product shall be sterile.

4.8 Residual amount of ethylene oxide (if applicable) If the mask has been sterilized or disinfected with ethylene oxide, the residual ethylene oxide content shall not exceed 10

μg/g.

5 Test methods

5.1 Appearance Carry out the test on at least 3 samples. Conduct visual inspection.

5.2 Structure and dimensions Carry out the test on at least 3 samples. Actually wear it and measure it with a general or special measuring tool.

5.3 Nose clip Carry out the test on at least 3 samples. Conduct visual inspection. Measure with general or special measuring tools, and perform actual wearing.

5.4 Mask strap

5.4.1 Earhook mask Carry out the test on at least 3 samples. Fix the main part of the mask above the two connection points of the test mask strap so that the mask maintains its natural shape and the two connection points are horizontal. Apply a static pulling force of 15 N in the middle of the mask belt to make the mask strap and the mask body in the same plane, as shown in Figure 1a). Maintain 5 s. Take the other side of the same mask and repeat the above test. If the sample mask strap and any connection points are not disconnected, the breaking strength is recorded as >=15 N. If disconnection occurs, record the disconnection location (mask strap or connection point) and the breaking strength < 15 N.

5.4.2 Strap mask Carry out the test on at least 3 samples. Fix the mask body so that the mask strap and the mask body are on the same plane. Apply a static pulling force of 10 N to the end of the mask strap in the direction shown in Figure 1b). Maintain 5 s. Take the other side of the same mask and repeat the above test. If the sample mask straps and connections are not disconnected, the breaking strength is recorded as >=10 N. If disconnection occurs, record the disconnection location (mask strap or connection) and the breaking strength < 10 N. If there is no fixed connection between the mask strap and the mask body, the mask strap shall be removed. One end is fixed, and the other end is loaded with a static tension force of 10 N. Maintain 5 s. If the mask strap is not broken, the breaking strength is recorded as >=10 N. If breakage occurs, record the breaking strength as < 10 N.

5.5 Bacterial filtration efficiency (BFE) Carry out the test on at least 3 samples. The test method is carried out according to the test method for bacterial filtration efficiency in YY 0469.Determine whether the results meet the requirements of 4.5.

5.6 Airflow resistance Number of samples. use at least 5 samples for testing. Test process. the test location shall be at the center of the mask (mouth and nose when worn). Select 3 non-overlapping test areas. The gas flow rate for testing needs to be adjusted to (8.0±0.2) L/min. The diameter of the sample test area is 25 mm. The test area is

4.9 cm2. Calculate airflow resistance (DeltaP) according to formula (1). Results are