YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0469-2023

Surgical masks

医用外科口罩

Issued on: November 22, 2023 **Implemented on: December 1, 2026**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 22 November 2023 by the National Medical Products Administration and takes effect on 1 December 2026.

It is a YY standard without the /T suffix: compliance is mandatory in China.

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 0469-2011 "Surgical mask". Compared with YY 0469- 2011, in addition to the structural adjustments and editorial modifications, the main technical changes in this document are as follows.

a) Supplement the changed scope (see Chapter 1 of this Edition; Chapter 1 of Edition 2011);

b) Delete the terms and definitions of particulate matter, sterilization, delayed hypersensitivity and irritation (see 3.3, 3.7, 3.8, 3.9 of Edition 2011). Add the terms and definitions for particle filtration efficiency (PFE) and airflow resistance (see 3.3, 3.6 of this Edition). Change the terms and definitions for surgical masks and particle filtration efficiency (see 3.1, 3.3 of this Edition; 3.1, 3.4 of Edition 2011);

c) Changed the requirements for structure and dimension, nose clip, mask strap, filtration efficiency, airflow resistance, microbial indicators, cytotoxicity, delayed hypersensitivity reaction (see 4.2, 4.3, 4.4, 4.6, 4.7, 4.9, 4.11.1, 4.11.3 of this Edition; 4.2, 4.3, 4.4, 4.6, 4.7, 4.9, 4.12, 4.13 of Edition 2011);

d) Change the titles of articles on resistance to synthetic blood penetration and airflow resistance (see 4.5 and 4.7 of this Edition; 4.5 and 4.7 of Edition 2011);

e) Change the test methods for mask straps, airflow resistance, microbial indicators, ethylene oxide residue, and biocompatibility (see 5.4, 5.7, 5.9, 5.10, 5.11 of this Edition; 5.4, 5.7, 5.9, 5.10, 5.11, 5.12, 5.13 of Edition 2011);

f) Change the requirements for marks (see Chapter 6 of this Edition; Chapter 6 of Edition 2011);

g) Change the method for preparing synthetic blood in Annex A to stipulate that other surfactants equivalent to Tween 20 can also be used (see A.1 of this Edition; A.1 of Edition 2011);

h) Change the requirements for the number of positive control bacteria in bacterial filtration efficiency (BFE) test method in Annex B. Add the average interception diameter calculation formula (see Annex B of this Edition; B.4 of Edition 2011). This document was proposed by National Medical Products Administration. This document shall be under the jurisdiction of National Standardization Working Group on Medical Protective Equipment (SAC/SWG 30). Versions of standard substituted by this document are. - It was YY 0469-2011 that was first issued in 2004: The first revision was in 2011; - This is the second revision. Surgical mask

1 Scope

YY 0469 is the mandatory Chinese standard for surgical masks, the masks worn in the operating theatre and in invasive procedures, a grade above the ordinary medical face mask of YY/T 0969. It specifies the technical requirements, test methods, marking, packaging, transport and storage for such masks, covering bacterial filtration efficiency, particle filtration, resistance to penetration by synthetic blood, breathing resistance and the microbiological cleanliness of the finished product. Because it carries the YY prefix without /T, compliance is compulsory in China: a mask cannot be sold as surgical without evidence against this text. It is also the reference customs and export contracts use to distinguish a surgical mask from a civilian one. The 2023 edition takes effect in December 2026 and supersedes the 2011 text the market has used for over a decade.

This document specifies the technical requirements, test methods, marks, packaging, transportation and storage for surgical masks. This document is applicable to disposable medical masks worn by medical staff in medical environments with potential risks of blood, body fluid, and secretion contamination and in invasive operating environments. This document does not apply to protective masks in medical and other working environments.

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 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

YY/T 0691-2008, Single-use medical face mask Part IV of Edition 2020 of the Pharmacopoeia of the People's Republic of China

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. 3.1 surgical mask A barrier that can cover the wearer's mouth, nose and jaw, and is used to prevent pathogenic microorganisms and droplets exhaled by the wearer from directly contaminating the patient or the surrounding environment, and to prevent the patient's body fluids, blood and other splashes from penetrating the mask and affecting the wearer. cause some damages. 3.2 synthetic blood A mixture of red dye, surfactant, thickener, and distilled water whose surface tension and viscosity can represent blood and other body fluids and have a color similar to blood. NOTE. The synthetic blood used in the tests in this document does not have all the characteristics of blood or body fluids, such as polarity (wetness), coagulability, and cellular material. 3.3 particle filtration efficiency; PFE Under specified testing conditions, the percentage of particulate matter filtered out by the mask.

4 Technical requirements

4.1 Appearance The appearance of the mask shall be neat and in good shape. There shall be no damage or stains on the surface.

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

4.3 Nose clip

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

4.3.2 Nose clips shall be made of malleable material. It shall be safe and secure, with no sharp protrusions. The length shall be no less than 8.0 cm. If a design is used to replace the

nose clip, the design shall be able to fix the nose clip and provide a basic seal when worn.

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 Resistance to synthetic blood penetration After 2 mL of synthetic blood is sprayed onto the outer side of the mask at a pressure of 16.0 kPa (120 mmHg), there shall be no penetration on the inner side of the mask.

4.6 Filtration efficiency

4.6.1 Bacterial filtration efficiency (BFE) The bacterial filtration efficiency of the mask shall be no less than 98%.

4.6.2 Particle filtration efficiency (PFE) The filtration efficiency of the mask against non-oily particles shall be no less than 80%.

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

4.8 Flame retardation properties Mask materials shall be made of non-flammable materials. The mask shall not burn for more than 5 s after leaving the flame.

4.9 Microbial indicators

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

4.9.2 Sterility (products supplied in a sterilized manner) Masks shall undergo a validated sterilization process. Products shall be sterile.

4.10 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 ug/g.

5 Test methods

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

5.2 Structure and dimension 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