ORIGINAL

Test Report

Scan to Query

Report Number： SGT-202602001-04

Device: SURGICAL FACK MASK

Report Date: 2026.03.10

Applicant Name: Rizhao Sanqi Medical & Health Articles Co., Ltd.

Applicant Address: No. 137 Rizhao North Road, High tech Zone, Rizhao City

Manufacturer: Rizhao Sanqi Medical & Health Articles Co., Ltd.

Manufacturer Address: No. 137 Rizhao North Road, High tech Zone, Rizhao City

Revision history of report			
Version	Details	Author/Editor	Issue Date
SGT-202602001-04	Initial version	Shujuan Cao	2026.03.10

Statement

All the information or parameter about product are provided by applicant.

The result of the commission test is only responsible for the sample(s) provided.

The test report is not valid without the signatures.

The test report is not valid if scribbled or altered.

Any dispute of the test report must be raised to the testing body within 15 days after the test report is received exceeding which the dispute will not be accepted.

Copy of the test report (except copy of the whole report) is not allowed without written approval.

The following sample (s) was/were submitted and identified on behalf of the client as:

Product name: SURGICAL FACK MASK

Size: 17.5×9.5cm

Code/Model: SQE-1001 (Type I)

Sample description: EN 14683:2025,Type I, Non-sterile

Sampling quantity: 15

Lot number:260205

Tests Conducted:

Date Received: 2026.03.02

Date Test Conducted: 2026.03.03~2026.03.10

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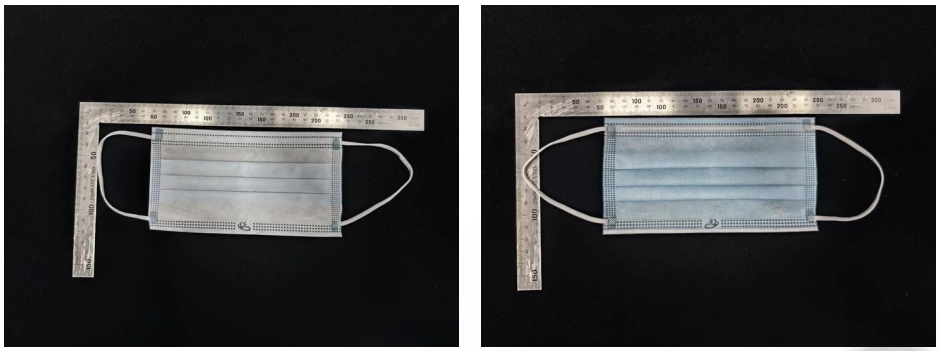
Inspection standard: EN 14683:2025



Test Sample

For details refer to attached page(s).

Conclusion:

The test sample's Bacterial Filtration Efficiency, Differential Pressure Test, Microbial Cleanliness Test meet the requirement of EN 14683:2025 Type I.

Section No.	Test Name	Test Standard	Sample Quantity	Judgement
SGT-202602001-04.01	Bacterial Filtration Efficiency	EN 14683:2025, Annex B	5	Pass
SGT-202602001-04.02	Differential Pressure Test	EN 14683:2025, Annex C	5	Pass
SGT-202602001-04.03	Microbial Cleanliness	EN 14683:2025, Annex D	5	Pass

Decision rule:
No need to consider the uncertainty associated with the test results according to the applicant.

Should you have any queries about the test report, please contact:

Approved by:

Name Raymond Luo
Title Supervisor

Checked by:

Betty Ruan

Name Betty Ruan
Title Reviewer

Prepared by:

Shujuan.Cao

Name Shujuan Cao
Title Author/Editor

Shanghai SUNGO Medical Technology Co., Ltd. 上海沙格医疗科技有限公司 检验检测专用章

Test Items, Method and Results：

SGT-202602001-04.01	**Bacterial Filtration Efficiency Test**
Ref. Specs Section	EN 14683:2025 Medical face masks - Requirements and test methods, Annex B
Date Tested	2026.03.05~2026.03.06
Sample Quantity	5
Sample No.	SGTS-20260200103.001~ SGTS-20260200103.005
Test Environment	22.4℃, 42%RH
Test Location	Room 218/219,Building B, No.958, Kangqiao East Road, Pudong New Area, Shanghai, China
Test Method	**1. Purpose:** For evaluating the bacterial filtration efficiency (BFE) of mask. **2. Identification of Test System and Reagents** 2.1 Staphylococcus aureus ATCC 6538; 2.2 Peptone water; 2.3 Tryptic Soy Broth; 2.4 Tryptic Soy Agar; **3. Test Specimen：** 3.1 Test specimen are complete masks or materials cut from mask. 3.2 Prior to testing, condition all test specimens for a minimum of 4h at (21± 5) ° C and (85± 5) % relative humidity. 3.3 The mask is installed with the outside facing up as a challenge surface in the experimental device. **4. Test Procedure：** 4.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/ml. The challenge delivery rate was maintained at 1200 to 3500 viable particle per test. 4.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min. 4.3 Deliver the challenge to the nebulizer using a syringe pump, Purge tubing and nebulizer of air bubbles. 4.4 Perform a positive control run without a test specimen to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates. 4.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to thenebulizer, immediately begin sampling the aerosol using the Anderson sampler. 4.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min. 4.4.3 Time the air pressure and Anderson sampler to run for 2 min. 4.4.4 At the conclusion of the positive control ran remove plates from the Anderson

	sampler. 4.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the outside of the specimen facing towards the bacterial challenge. 4.6 Repeat the challenge procedure for each test specimen. 4.7 Repeat a positive control after completion of the sample set. 4.8 Perform a negative control run by collecting a 2 min sample of the aerosol chamber, No bacterial challenge should be pumped into the nebulizer during the collection of the negative control. 4.9 Incubate agar plates at (37±2)℃for (48±4) h. 4.10 Count each of the six-stage plates of the Anderson sampler.
Calculation	Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler.The filtration efficiency percentages are calculated as follows: BFE% = (C-T) / C×100 C = average plate count total for test controls T= plate count total for test sample Note: The plate count total is available upon request. All Test method acceptance criteria were meet. Test Side: Outside BFE Test Area: ~49cm^2 BFE Flow Rate:28.3 Litres per minute (L/min) Condition Parameters: 85±5% relative humidity(RH) and 21±5℃ for a minimum of 4 hours Test Specimen Dimensions: ~175mm×~95mm Positive Control Average: 1.805×10^3 (Specimen SGTS-20260200103.001- SGTS-20260200103.005); Negative Control Average: <1 CFU MPS: 3.0±0.3μm;
Acceptance Criteria	BFE≥95%
Deviation	None
Test Results	

Sample No.	BFE (%)
SGTS-20260200103.001	99.3
SGTS-20260200103.002	99.1
SGTS-20260200103.003	99.8
SGTS-20260200103.004	98.4
SGTS-20260200103.005	99.9

Test Instruments

Equipment No.	Equipment Name	Calibration Validity
SGT-MB001	Biosafety cabinet	2027.01.05
SGT-MB002	Ultra-clean table	2027.01.05
SGT-MB063	Reciprocal or Rotator Mechanical Shaker	2026.05.18

	SGT-MB010	BFE bacteria filtration efficiency tester	2027.01.05

Observations & Remarks

None

Conclusion

The test results are in accordance with the requirements.

SGT-202602001-04.02	**Differential Pressure Test**
Ref. Specs Section	EN 14683:2025 Medical face masks - Requirements and test methods, Annex C
Date Tested	2026.03.04
Sample Quantity	5
Sample No.	SGTS-20260200103.006~SGTS-20260200103.010
Test Environment	24.5℃,32%RH
Test Location	Room 218/219,Building B, No.958, Kangqiao East Road, Pudong New Area, Shanghai, China
Test Method	**1. Purpose:** The test performed to measure the breathability of a surgical mask. **2. Identification of Test System and Reagents** 2.1 Test specimen are complete masks or shall be cut from masks, each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter. 2.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21± 5)℃ and(85± 5)% relative humidity. **3. Test procedure：** 3.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min. 3.2 The test specimen is placed across the 2.5 cm diameter orifice (total area 4.9 cm^2) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air. 3.3 The pump is started and that the tested area of the specimen will be in line and across the flow of air. 3.4 The manometers M1 and M2 are read and recorded. 3.5 The procedure described in steps 3.1~3.4 is carried out on 5 different areas of the mask and reading averaged.
Calculation	For each test material calculate the differential pressure ΔP of each tested area as follows: $\Delta P = X_{m1} - X_{m2}$ Where X_{m1} is the pressure in Pa, measured by manometer M1 - low pressure side of the material; X_{m2} is the pressure in Pa, measured by manometer M2 - high pressure side of the material; ΔP is the differential pressure of test material expressed in Pa.
Acceptance Criteria	Delta P: ≤200 Pa
Deviation	None

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Test Results

Sample No.	Delta P(Pa)					
	Location No.					Average
	1	2	3	4	5	
SGTS-20260200103.006	93.3	84.0	84.1	92.0	87.2	88.1
SGTS-20260200103.007	91.5	91.5	84.9	87.2	92.2	89.5
SGTS-20260200103.008	83.9	101.5	82.7	97.4	84.7	90.0
SGTS-20260200103.009	99.6	85.7	89.0	82.1	91.0	89.5
SGTS-20260200103.010	80.1	88.4	89.9	85.7	84.6	85.7

Test Instruments

Equipment No.	Equipment Name	Calibration Validity
SGT-ME002	Medical mask gas exchange pressure tester	2027.01.04

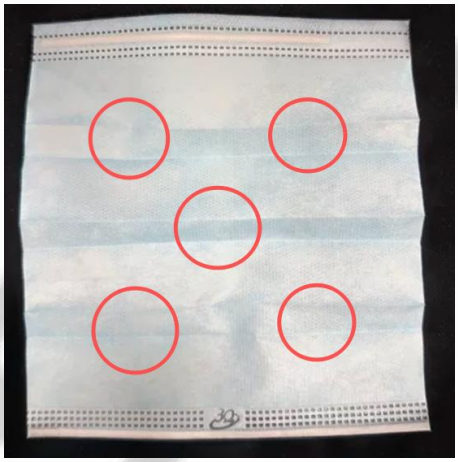
Observations & Remarks

None

Conclusion

The test results are in accordance with the requirements.

Pictures



Test Location of Sample

SGT-202602001-04.03	**Microbial Cleanliness**
Ref. Specs Section	EN 14683:2025 Medical face masks - Requirements and test methods, Annex D
Date Tested	2026.03.03~2026.03.10
Sample Quantity	5
Sample No.	SGTS-20260200103.011~SGTS-20260200103.015
Test Environment	23.8℃,38%RH
Test Location	Room 218/219,Building B, No.958, Kangqiao East Road, Pudong New Area, Shanghai, China
Test Method	**1. Purpose:** For evaluating the microbial cleanliness of mask. **2.Test specimen:** 2.1 Aseptic packaging, wipe the outer packaging with alcohol before testing. **3.Identification of Test System and Reagents:** 3.1 Peptone water 3.2 Tryptic Soy Agar (TSA) 3.3 Schalds glucose AGAR medium (SDA) contains chloramphenicol 3.4 NaCl 3.5 Peptone 3.6 Tween 20 **4. Test Procedure:** 4.1 Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). 4.2 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. 4.3 After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. 4.4 Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. 4.5 The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. 4.6 Correction factor test: Inoculation suspensions containing approximately 100 CFU Bacillus atrophicum (ATCC9372) per 0.1mL were prepared and three sterile samples were inoculated. After elution filtration according to method 1, the filter membrane was attached to the TSA plate and cultured at 30℃~35℃ for 1-3 days, and counted.
Calculation	1. R= X/Z×100%　CF=1/R X: The average number of eluted colonies in 3 samples, CFU;

	Z: Number of inoculated spores, CFU; R: Recovery rate; CF: Correction factor 2. The total bioburden (CFU/g)=3× (number of aerobic bacteria colonies + number of fungal colonies) × correction factor/sample quality
Acceptance Criteria	≤30cfu/g
Deviation	None

Test Results

Sample No.	Weight (g)	Aerobic (CFU/100ml)	Fungal (CFU/100ml)	Correction Factor	Total Bioburden (CFU/ g)
SGTS-20260200103.011	3.05	1	0	1.2	1
SGTS-20260200103.012	3.05	0	0	1.2	<2
SGTS-20260200103.013	3.04	0	1	1.2	1
SGTS-20260200103.014	3.01	0	0	1.2	<2
SGTS-20260200103.015	3.04	2	0	1.2	2

Test Instruments

Equipment No.	Equipment Name	Calibration Validity
SGT-MB002	Ultra-clean table	2027.01.05
SGT-MB038	Electronic balance	2027.01.04
SGT-MB006	Microbial limit testing apparatus	NA
SGT-MB024	Reciprocal or Rotator Mechanical Shaker	2027.01.05
SGT-MB064	Mildew Incudbator	2026.05.18
SGT-MB004	High-pressure steam sterilizer	2026.05.18

Observations & Remarks

None

Conclusion

The test results are in accordance with the requirements.

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The End of Report