



**SUBJECT** Physical & Microbiological Test

**TEST LOCATION** TÜV SÜD China

TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Jiangsu Zhiyu Medical Instrument Co., Ltd

**CLIENT ADDRESS** No.88, Nanyuan Road, Industrial Park, West Taixing, Jiangsu Province, China

**TEST PERIOD** 16-Apr-2020~24-Apr-2020

**Prepared By**

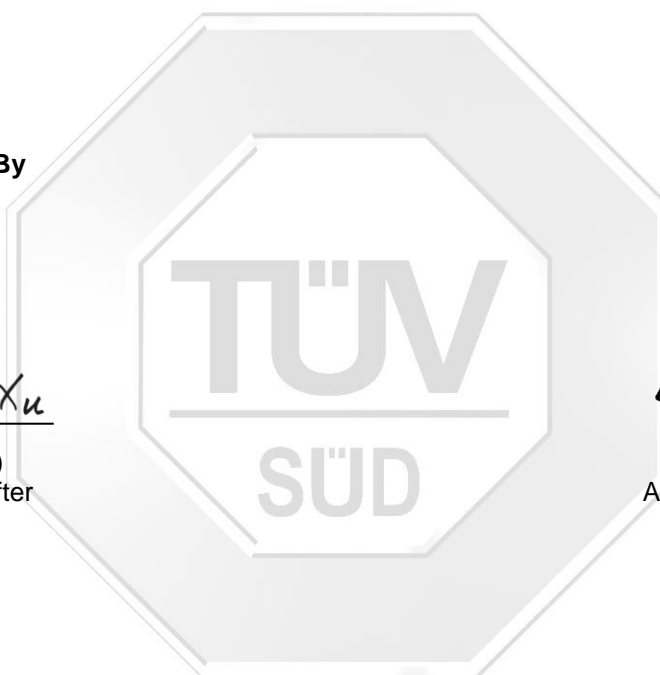
Bella Xu

(Bella Xu)  
Report Drafter

**Authorized By**

Leo Liu

(Leo Liu)  
Authorized Signatory



**Note:** (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

**Chemical/Microbiology Laboratory:**  
TÜV SÜD Products Testing (Shanghai) Co.,  
Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai  
201108  
P.R. China

Phone : +86 (21) 6037 6375  
Fax : +86 (21) 6037 6345  
Email: food.chem@tuv-sud.cn  
Webpage: www.tuv-sud.cn

**Regional Head Office:**  
TÜV SÜD Certification and Testing  
(China) Co., Ltd.  
No.151 Heng Tong Road Shanghai  
200 070 P.R.China

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**TEST REPORT**

Sample Description : Disposable Medical Face mask  
 Sample Quantity : 50 pieces  
 Lot Number/Batch Code : 20200320  
 Specification : /  
 Size : 175x95mm  
 Type of Mask : /  
 Brand Name : /

Remark: The above information was provided by applicant.

**Summary of Test Results**

No.	Test Item	Test Standard	Test Standard Type I	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 95	Pass
2	Differential Pressure Test (Pa/cm <sup>2</sup> )	EN 14683:2019+AC:2019(E) Annex C	< 40	Pass
3	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;  
 Fail = Fail customer requirements;  
 # = No comment;  
 N.D. = Not detected.

**Photo of Samples**



### Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 98.1% Specimen 2#: 98.2% Specimen 3#: 98.4% Specimen 4#: 98.2% Specimen 5#: 98.4%
2	Differential Pressure Test	28.6 Pa/cm <sup>2</sup>
3	Microbial Cleanliness Test	Specimen 1#: 1 CFU/g Specimen 2#: <1 CFU/g Specimen 3#: 1 CFU/g Specimen 4#: 1 CFU/g Specimen 5#: 1 CFU/g

### Bacterial Filtration Efficiency (BFE) Test

#### 1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

#### 2. Sample description was given by client

Sample description : Disposable Medical Face mask  
Specification : /  
Lot Number : 20200320  
Sample Receiving Date : 2020-04-16

#### 3. Test Method

EN 14683:2019+AC:2019(E) Annex B

#### 4. Apparatus and materials

- 4.1 *Staphylococcus aureus* ATCC 6538.
- 4.2 Peptone water.
- 4.3 Tryptic Soy Broth(TSB).
- 4.4 Tryptic Soy Agar(TSA).
- 4.5 Bacterial filtration efficiency test apparatus.
- 4.6 Six-stage viable particle Anderson sampler.
- 4.7 Flow meters.

#### 5. Test specimen

- 5.1 As requested by client, take a total of 5 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

#### 6. Procedure



- 6.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately  $5 \times 10^5$  CFU/mL.
- 6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
- 6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
- 6.4 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.
  - 6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the Anderson sampler.
  - 6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  - 6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  - 6.4.4 At the conclusion of the positive control run, remove plates from the Anderson sampler.
- 6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm<sup>2</sup>).
- 6.6 Repeat the challenge procedure for each test specimen.
- 6.7 Repeat a positive control after completion of the sample set.
- 6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
- 6.9 Incubate agar plates at  $(37 \pm 2)^\circ\text{C}$  for (20 to 52) h.
- 6.10 Count each of the six-stage plates of the Anderson sampler.

## 7. 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:

$$\text{BFE} = (C - T) / C \times 100$$

*T* is the total plate count for the test specimen.

*C* is the mean of the total plate counts for the two positive controls.



8. Test results\*

<i>P</i> Value Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	23	56	0	0	2	0	0	0
2	52	150	0	0	0	0	0	0
3	134	198	0	0	0	0	0	0
4	230	308	0	1	0	3	1	5
5	1241	1314	0	31	24	23	27	25
6	670	606	0	16	19	15	16	11
Total ( <i>T</i> ), CFU	2350	2632	<1	48	45	41	44	41
Average ( <i>C</i> ), CFU	$2.5 \times 10^3 = (P_A + P_B) / 2$							
BFE, %				98.1	98.2	98.4	98.2	98.4
Requirements	≥ 95							
Remarks	<i>P</i> is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. <i>T</i> is the total of <i>P</i> value for the test specimen. <i>C</i> is the mean of the total of <i>P</i> value of the two positive controls.							

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## Differential pressure Test

### 1. Purpose

The purpose of the test was to measure the differential pressure of masks.

### 2. Sample description was given by client

Sample description : Disposable Medical Face mask  
Specification : /  
Lot Number : 20200320  
Sample Receiving Date : 2020-04-16

### 3. Test Method

EN 14683:2019+AC:2019(E) Annex C

### 4. Apparatus and materials

Differential pressure testing instrument

### 5. Test specimen

- 5.1 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.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4 h at  $(21 \pm 5)^\circ\text{C}$  and  $(85 \pm 5)\%$  relative humidity.

### 6. Procedure

- 6.1 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.
- 6.2 The pretreated specimen is placed across the orifice (total area  $4.9\text{cm}^2$ , test area diameter 25mm) and clamped into place so as to minimize air leaks.
- 6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
- 6.4 The differential pressure is read directly.
- 6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm <sup>2</sup> )	Average (Pa/cm <sup>2</sup> )	Requirements	Judgement
1#	27.7	28.6	< 40	Pass
2#	27.8			
3#	28.2			
4#	29.9			
5#	29.2			

## Microbial Cleanliness Test

### 1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

### 2. Sample description was given by client

Sample description : Disposable Medical Face mask  
Specification : /  
Lot Number : 20200320  
Sample Receiving Date : 2020-04-16

### 3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

### 4. Apparatus and materials

- 4.1 Orbital shaker.
- 4.2 0.45 um filter.
- 4.3 Tryptic Soy Agar (TSA).
- 4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
- 4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
- 4.6 Extraction apparatus.

### 5. Test specimen

- 5.1 As requested by client, take a total of 5 mask samples.
- 5.2 Mask samples for testing are provided in the original primary packaging.
- 5.3 Condition at (18 to 26)°C and (45 to 65)% relative humidity during testing.

### 6. Procedure

- 6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
- 6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
- 6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
- 6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
- 6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
- 6.6 Calculate the colonies of each agar plate.

### 7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.



Results\*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	1	0	1	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be $\leq 30$ CFU/g tested.	Pass
2#	0	0	<1		
3#	0	1	1		
4#	1	0	1		
5#	0	1	1		

Note:

- 1.\*denotes this test was carried out by external laboratory assessed as competent.
- 2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

