

Report No.: BT20042801619

TL-787
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Customer Information:

Customer. : Changzhou shuangma medical devices co.,ltd
Address. : San He Kou Development Zone, Zhenglu Town, Tianning District,
Changzhou City

Sample Information:

Sample Name. : Single-use medical face mask
17.5cm×9.5cm 17.5cm×9.5cm
Sample Description. : Samples in good condition
Sampled Method. : All parts were received from customer
Receipt Date. : 2020-04-28

Testing Information:

Test Items. : Bacterial Filtration Efficiency(BFE) , etc.
Test Reference. : EN 14683: 2019
Test Result. : Please refer to the following pages

Written by: Arzi Gul Inspected by: Yan'er Li Approved by: Steven zha
Date: 2020-05-06 Date: 2020-05-06 Date: 2020-05-06



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Test Report

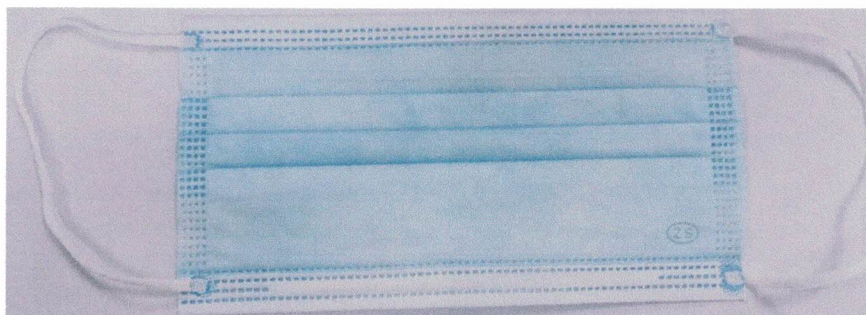
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1、 Sample List

Manufacturer	Sample Name	Specification	Material	Lot
Changzhou shuangma medical devices co.,ltd	Single-use medical face mask	17.5cm×9.5cm	/	20200308

2、 Sample Photos



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Appendix 1: Bacterial Filtration Efficiency(BFE)
1.1.Reference Standard Item: EN 14683-5.2.2 BFE

1.2.Environmental Condition: 24℃, 58%RH

1.3.Strain, Medium and Reagent information:

Staphylococcus Aureus (ATCC6538);

Peptone Agar Medium (20191205);

Peptone Liquid Medium (1085071);

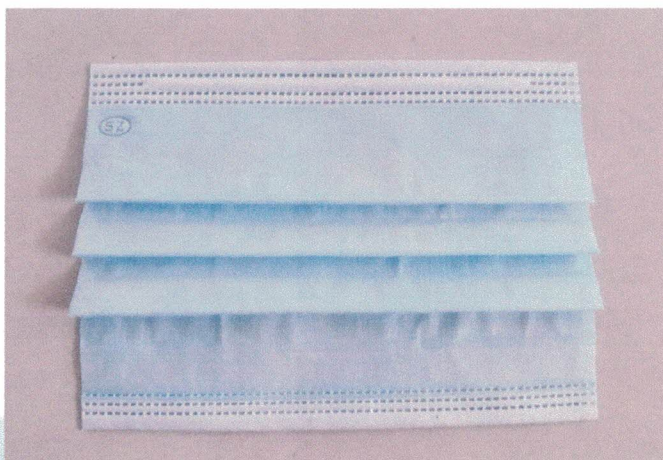
PH7.0 Sodium Chloride-peptone Buffer (1071461);

1.4.Test Parameters:

Air flow rate (double way)	57 L/min
Mean particle diameter of bacterial aerosol	(3.0±0.3)μm

1.5.Result:

Determination of bacterial suspension concentration									
Plate 1(CFU)		Plate 2(CFU)			Dilution level		Concentration(CFU/mL)		
58		60			10 ⁻⁴		5.9×10 ⁵		
Groups		Plate 1	Plate 2	Plate 3	Plate 4	Plate 5	Plate 6	Total	BFE
Negative Control	r	0	0	0	0	0	0	0	/
	p	0	0	0	0	0	0	0	
Positive Control 1	r	11	38	56	317	379	42	843	/
	p	11	40	60	629	1179	44	1963	
Positive Control 2	r	55	62	118	375	388	45	1043	/
	p	59	67	140	1109	1408	48	2831	
Sample 1	r	0	0	0	0	2	0	2	99.92%
	p	0	0	0	0	2	0	2	
Sample 2	r	0	0	0	1	1	3	5	99.79%
	p	0	0	0	1	1	3	5	
Sample 3	r	0	0	0	0	0	1	1	99.96%
	p	0	0	0	0	0	1	1	
Sample 4	r	0	0	0	0	1	3	4	99.83%
	p	0	0	0	0	1	3	4	
Sample 5	r	0	0	0	3	0	0	3	99.87%
	p	0	0	0	3	0	0	3	

1.6. Sample after Test:


About 12 cm*12cm

Appendix 2: Differential Pressure (Delta P)
2.1.Reference Standard Item: EN 14683-5.2.3 Breathability

2.2.Environmental Conditions: 23.1°C, 52%RH

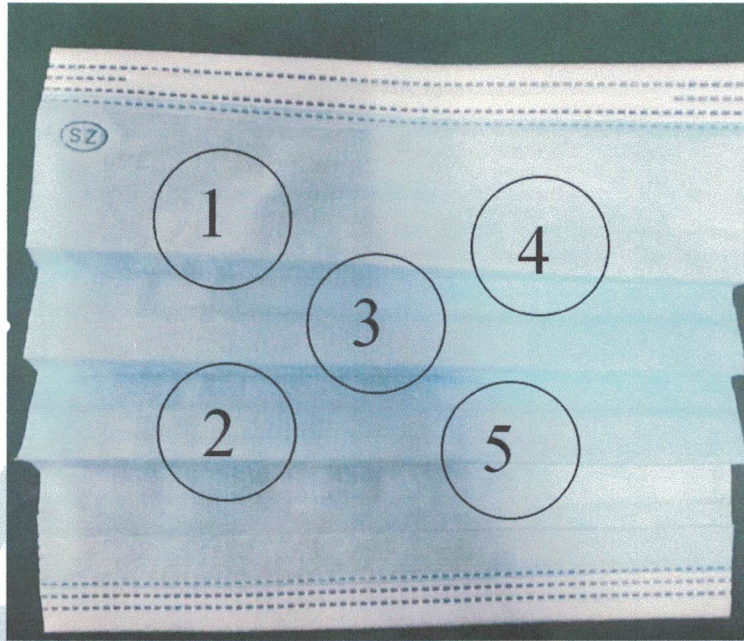
2.3.Test Parameters:

Air flow rate (double way)	8 L/min
Sample Diameter	φ25 mm
Test area	4.9 c m ²

2.4.Result:

NO.	Position 1 (Pa)	Position 2 (Pa)	Position 3 (Pa)	Position 4 (Pa)	Position 5 (Pa)	Average (Pa)	Delta P (Pa/cm ²)
Sample 1	113.8	102.9	120.0	112.8	111.8	112.3	22.91
Sample 2	116.5	120.6	104.6	110.6	117.6	114.0	23.26
Sample 3	114.5	107.5	112.1	112.1	115.1	112.3	22.91
Sample 4	108.1	107.1	118.9	104.1	102.2	108.1	22.06
Sample 5	102.3	105.3	106.0	112.2	113.5	107.9	22.01

2.5. Sample after Test:



Test location of sample

Appendix 3: Splash resistance

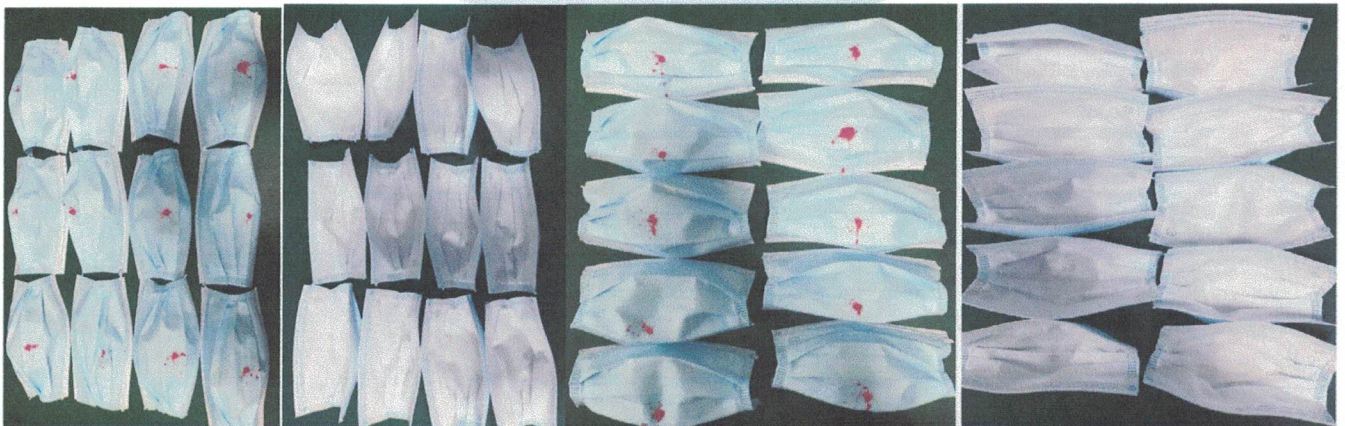
3.1.Reference Standard Item: EN14683-5.2.4 Splash resistance; ISO 22609: 2004

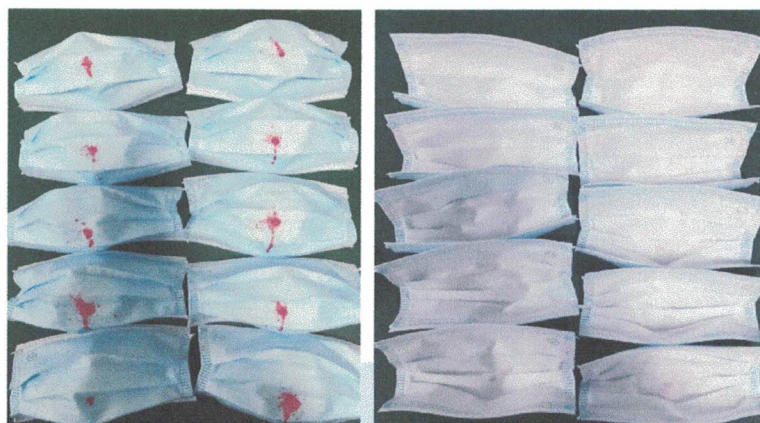
3.2.Environmental Condition: 23.1°C, 52%RH

3.3.Test Parameters:

Pressure (KPa)	Velocity (cm/s)	Time (s)
16.0	550	0.66

3.4. Sample after Test:





Picture : 16.0 KPa Sample after Test

3.5.Result:

The samples were tested under pressure of 16.0kPa, no synthetic blood penetration on the medial side.

Appendix 4: Microbial cleanliness

4.1.Reference Standard Item: EN 14683-5.2.5 Microbial cleanliness (Bioburden); EN ISO 11737-1:2018

4.2. Reagents:

SDA (Lot No:20190912)

TSA (Lot No:20190613)

Sodium chloride-peptone buffer (Lot No:20190820)

4.3. Sample preparation:

5 samples were randomly selected for the experiment.

4.4. Test method:

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. 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. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30°C and 7 days at 25°C for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

4.5. Statistical method:

Count according to the principle of colony count.

4.6. Results of the test:

Sample number	Weight g	Aerobic cfu/100ml	Fungal cfu /100ml	Total Bioburden cfu /sample	Total Bioburden cfu /g
1	3.2	16	3	57	17.8
2	3.2	14	2	48	15.0
3	3.2	13	3	48	15.0
4	3.3	14	3	51	15.5
5	3.2	13	2	45	14.1

***** End *****

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