BeFitLab 百帆测试

Test Report

Report No.: BT20031901616-1

Customer Information:

Customer. . . . . : JIANGSU JINLU GROUP MEDICAL DEVICE CO.,LTD.

Address. . . . . : Jinfeng Zhangjiagang Jiangsu China

Sample Information:

Sample Name. . . . . : Disposable Face Mask

Sample Specification. . . . : 17cm*9cm

Sample Description. . . . . : Samples in good condition

Sampled Method. . . . . : All parts were received from customer

Receipt Date. . . . . : 2020-03-19

Testing Information:

Test Items. . . . . : Appearance、Dimension deviation、Nose Clip , etc.

Test Reference. . . . . : EN14683-2019

Test Result. . . . . : Please refer to the following pages

Written by:	Yawei Li	Inspected by:	Shufeng Wu	Approved by:	Steven Zhu
Date:	2020-03-30	Date:	2020-03-30	Date:	2020-03-30

BTT INTERNATIONAL TESTING SERVICE CERTIFICATION BTT

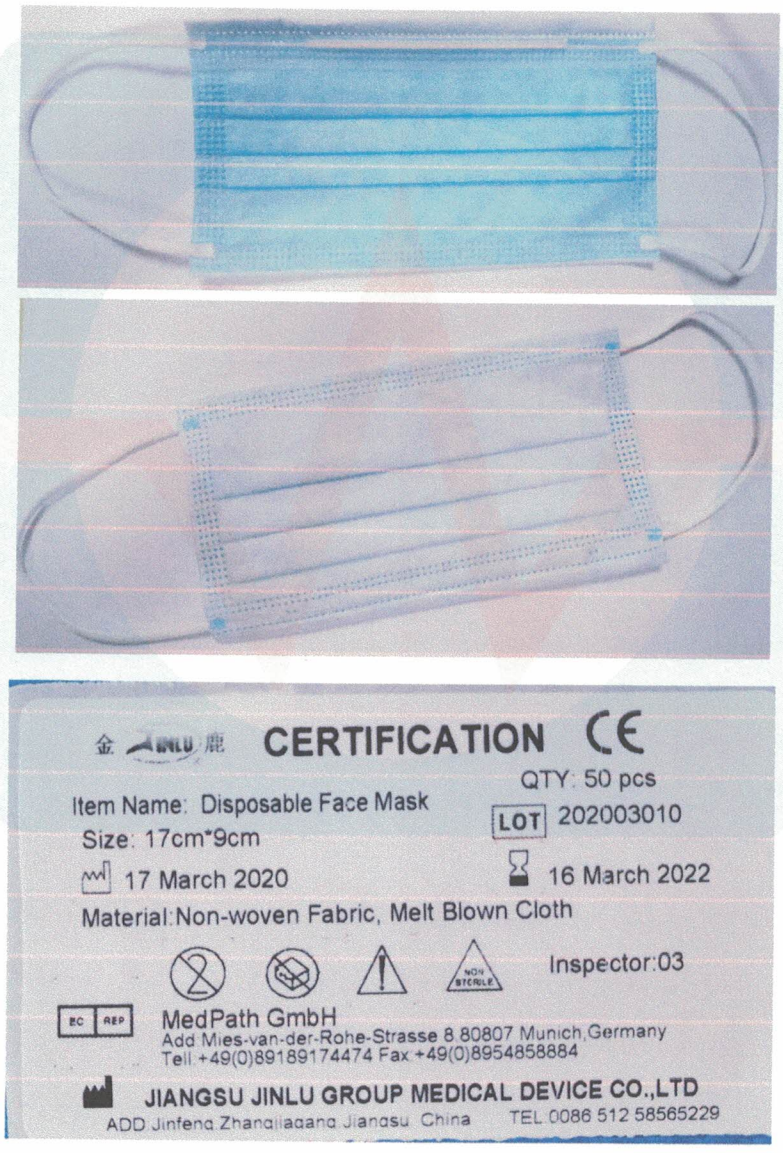
BEFITLAB TEST TECHNOLOGY COMPANY LIMITED

Member of International Standards Certification (ISC) Group

1、Sample List

Manufacturer	Sample Name	Specification	Material	Lot
JIANGSU JINLU GROUP MEDICAL DEVICE CO.,LTD.	Disposable Face Mask	17cm*9cm	Non-woven Fabric, Melt Blown Cloth	202003010

2、Sample Photos



Disposable Face Mask 17cm*9cm

Appendix 1: Appearance

Reference Standard Item: EN14683-5.1.1 Materials and construction			
Test Item	Test Results		Standard Requirement
Appearance	001#	Pass	The appearance of the mask should be clean, the shape is intact, the surface must not have the tear hole, the stain.
	002#	Pass	
	003#	Pass	

Appendix 2: Construction and Dimension

Reference Standard Item: EN14683-5.1.2 Design				
Test Item	Test Results			Standard Requirement
Dimension deviation	001#	length	+ 0.3cm	Design tolerance ± 1cm (Customer Requirements)
		width	+ 0.5cm	
	002#	length	+ 0.4cm	
		width	+ 0.6cm	
	003#	length	+ 0.3cm	
		width	+ 0.5cm	

Appendix 3: Nose Clip

Reference Standard Item: EN14683-5.1.2 Design			
Test Item	Test Results		Standard Requirement
Nose Clip	001#	Pass	Masks should be fitted with nose clips made of plastic materials.
	002#	Pass	
	003#	Pass	
	001#	9.8cm	Nose clip length should be not less than 8.0cm (Customer Requirements)
	002#	9.8cm	
	003#	9.7cm	

Appendix 4: Bacterial Filtration Efficiency(BFE)

4.1.Reference Standard Item: EN14683-5.2.2 BFE

4.2.Environmental Condition: 23℃, 50%RH

4.3.Strain, Medium and Reagent information:

Staphylococcus Aureus (ATCC6538);

Peptone Agar Medium (20191205);

Peptone Liquid Medium (1085071);

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

4.4.Test Parameters:

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

4.5.Result:

Determination of bacterial suspension concentration									
Plate 1(CFU)		Plate 2(CFU)		Dilution level		Concentration(CFU/mL)			
60		64		10^{-4}		6.2×10^{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	6	8	128	262	384	33	821	/
	p	6	8	154	426	1288	34	1916	
Positive Control 2	r	13	11	102	372	382	113	993	/
	p	13	11	118	1064	1241	133	2580	
Sample 1	r	0	0	0	5	4	2	11	99.51%
	p	0	0	0	5	4	2	11	
Sample 2	r	0	0	0	2	2	0	4	99.82%
	p	0	0	0	2	2	0	4	
Sample 3	r	0	0	0	5	2	1	8	99.64%
	p	0	0	0	5	2	1	8	
Sample 4	r	0	0	0	4	1	1	6	99.73%
	p	0	0	0	4	1	1	6	

	Sample 5	r	0	0	0	5	3	1	9	99.60%	
		p	0	0	0	5	3	1	9		

4.6. Sample after Test:

About 12 cm*12cm

Appendix 5: Differential Pressure (Delta P)

5.1.Reference Standard Item: EN14683-5.2.3 Breathability

5.2.Environmental Conditions: 21℃, 50%RH

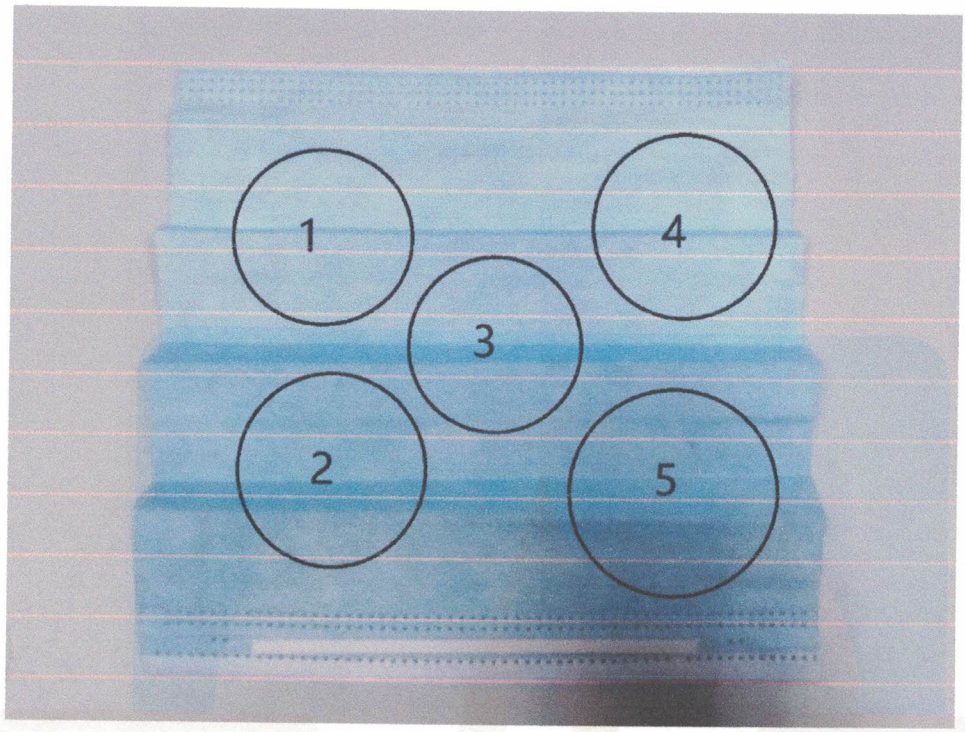
5.3.Test Parameters:

Air flow rate (double way)	8 L/min
Sample Diameter	φ25 mm
Test area	4.9 c ㎡

5.4.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	47.6	53.3	58.1	54.7	48.6	52.5	10.71
Sample 2	41.2	47.5	54.2	46.9	51.4	48.2	9.84
Sample 3	51.0	51.9	58.1	50.3	55.6	53.4	10.89
55.5	54.2	62.4	57.9	60.9	58.2	11.87	55.5
50.7	56.1	56.5	56.2	51.5	54.2	11.06	50.7

5.5. Sample after Test:



Test location of sample

Appendix 6: Splash resistance

6.1.Reference Standard Item: EN14683-5.2.4 Splash resistance

6.2.Environmental Condition: 21℃, 50%RH

6.3.Test Parameters:

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

6.4. Sample after Test:

Picture ： 16.0 KPa Sample after Test

6.5.Result:

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

Appendix 7: Microbial cleanliness

7.1.Reference Standard Item: EN 14683-5.2.5 Microbial cleanliness (Bioburden)

7.2. Reagents:

SDA（Lot No:180912）

TSA（Lot No:20190613）

Sodium chloride-peptone buffer（Lot No:180820）

7.3. Sample preparation:

5 samples were randomly selected for the experiment.

7.4. 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℃ and 7 days at 25℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

7.5. Statistical method:

Count according to the principle of colony count.

7.6. Results of the test:

Sample number	Weight g	Aerobic cfu/100ml	Fungal cfu /100ml	Total Bioburden cfu /sample	Total Bioburden cfu /g
1	3.1	15	1	48	15.5
2	3.1	16	3	57	18.4
3	3.2	22	2	72	22.5
4	3.1	18	3	63	20.3
5	3.3	20	5	75	22.7

****** End ******

Notice Items:

1. It is not valid if the report without our stamp.
2. This report must not be altered, increased or deleted.
3. The report is just responsible for the tested sample.
4. The sample(s) information was/were submitted and identified on behalf of the client.
5. Any questions on the report should be put forward within fifteen days since the date on which you receive the report, and overdue is inadmissible.
6. The report must not be partially duplicated except in full, without prior written approval of the company.