BeFitLab 百帆测试

Test Report

TL-787

Report No.: BT20032701635

Customer Information:

Customer. . . . . : Jiangxi Sanxin Medtec Co., Ltd.

Address. . . . . : No.999 Fushan Road, XiaoLan Economic Development Zone, Nanchang,Jiangxi

Sample Information:

Sample Name. . . . . : Disposable Medical Face Masks

Sample Specification. . . . : Model: Type A (earclip type); Specification:medium size

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

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

Receipt Date. . . . . : 2020-03-27

Testing Information:

Test Items. . . . . : Bacterial Filtration Efficiency(BFE) , etc.

Test Reference. . . . . : EN 14683：2019

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

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Written by:	Inspected by:	Approved by:
Arzi gul	Yawei Li	Steven Zhu
Date: 2020-04-03	Date: 2020-04-03	Date: 2020-04-03

BTT INTERNATIONAL TESTING SERVICE CERTIFICATION

BEFITLAB TEST TECHNOLOGY COMPANY LIMITED

Member of International Standards Certification (ISC) Group

Test Report

1、Sample List

Manufacturer	Sample Name	Specification	Material	Lot
Jiangxi Sanxin Medtec Co., Ltd.	Disposable Medical Face Masks	Model: Type A (earclip type); Specification: medium size	Nonwoven fabric And Melt-blown fabric	20022603

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: 23℃, 60%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	14	45	95	313	377	43	887	/
	p	14	48	108	610	1142	45	1967	
Positive Control 2	r	22	55	116	320	380	44	937	/
	p	23	59	137	644	1198	47	2108	
Sample 1	r	0	1	1	7	22	15	46	97.69%
	p	0	0	1	7	23	15	47	
Sample 2	r	0	0	1	3	21	5	30	98.48%
	p	0	0	1	3	22	5	31	
Sample 3	r	0	0	2	3	20	7	32	98.38%
	p	0	0	2	3	21	7	33	
Sample 4	r	0	0	1	2	22	8	33	98.33%
	p	0	0	1	2	23	8	34	
Sample 5	r	0	0	2	3	23	6	34	98.28%
	p	0	0	2	3	24	6	35	

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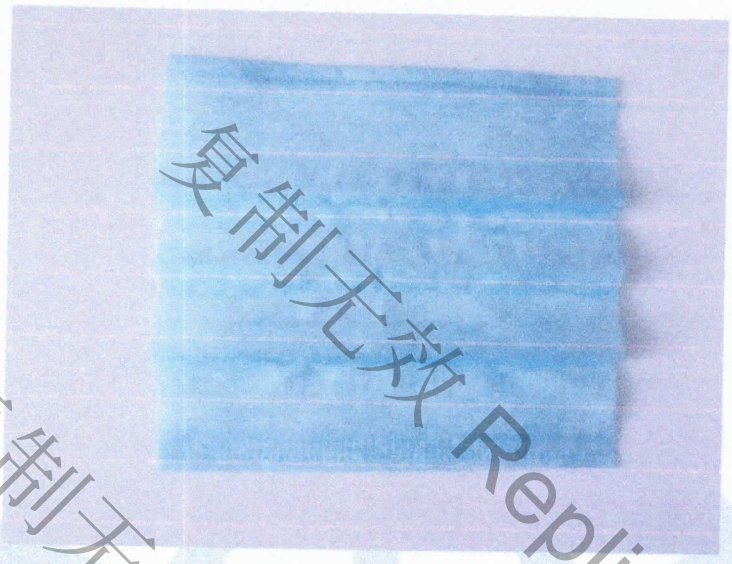
1.6. Sample after Test:



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: 20.3℃, 56%RH

2.3.Test Parameters:

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

2.4.Result:

NO.	Position 1 (Pa)	Position 2 (Pa)	Position 3 (Pa)	Position 4 (Pa)	Position 5 (Pa)	Average (Pa)	Delta P (Pa/cm²)
Sample 1	80.8	84.7	73.6	85.6	73.1	79.6	16.24
Sample 2	67.2	90.7	73.5	65.7	84.2	76.3	15.56
Sample 3	77.6	84.8	73.2	75.2	82.2	78.6	16.04
Sample 4	78.4	76.3	70.1	83.8	65.2	74.8	15.26
Sample 5	89.8	85.1	76	89.9	83.4	84.8	17.31

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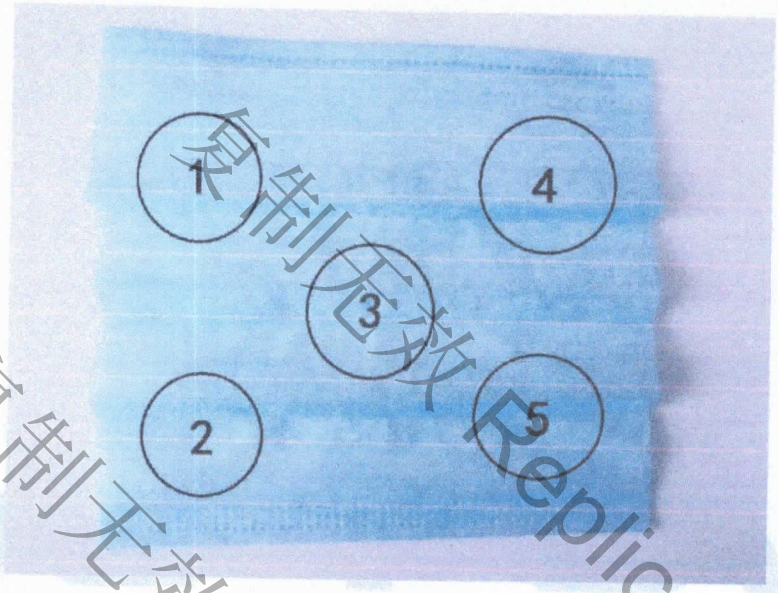
2.5. Sample after Test:



Test location of sample

Appendix 3: Splash resistance

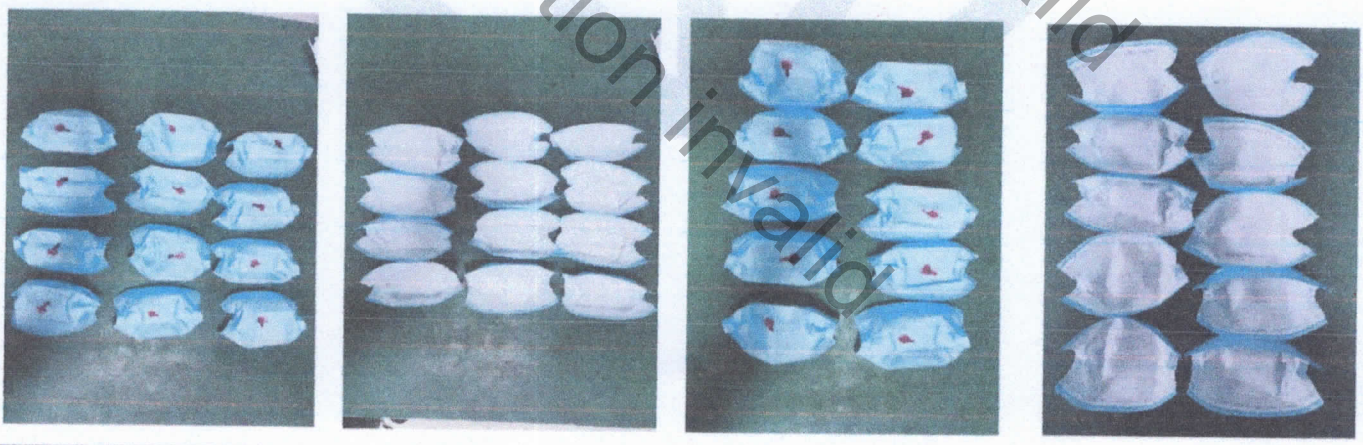
3.1.Reference Standard Item: EN14683-5.2.4 Splash resistance; ISO 22609: 2004

3.2.Environmental Condition: 20.3℃, 56%RH

3.3.Test Parameters:

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

3.4. Sample after Test:



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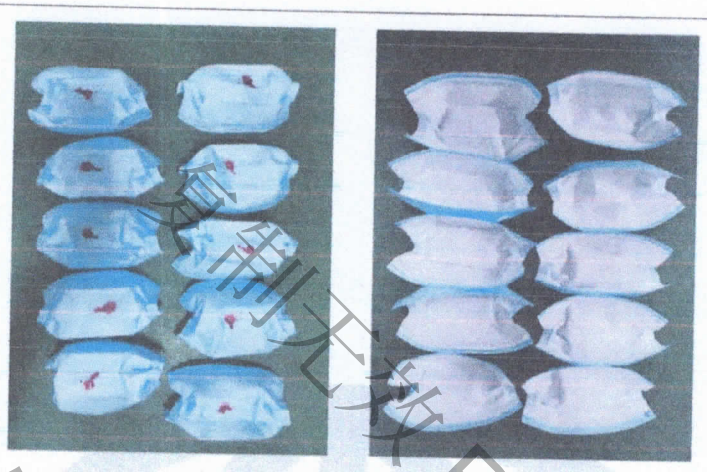

Picture ： 16.0 KPa Sample after Test

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:180912）

TSA（Lot No:20190613）

Sodium chloride-peptone buffer（Lot No:180820）

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℃ and 7 days at 25℃ 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.

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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	18	5	69	21.6
2	3.2	21	3	72	22.5
3	3.1	16	1	51	16.5
4	3.2	17	4	63	19.7
5	3.2	19	2	63	19.7

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

Notice Items:

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2. This report must not be altered, increased or deleted.
3. The report is just responsible for the tested sample.
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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.
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