

Report No.: BT20050901625

Customer Information:

Customer..... : Wenzhou Meiyi Medical Device Co.,Ltd
Address..... : Hengjie Industrial,Xianjiang Street ,Ruian
Wenzhou,Zhe jiang,China

Sample Information:

Sample Name.....: 3D FACIAL PROTECTIVE MASK(KN95 MASK)
Sample Specification....: MY-002
Sample Classification...: FFP2
Sample Description.....: Samples in good condition
Sampled Method.....: All parts were received from customer
Receipt Date.....: 2020-05-09

Testing Information:

Test Items.....: Leakage、 Penetration of filter material , etc.
Test Reference.....: EN 149: 2001+A1: 2009
Test Result.....: Please refer to the following pages

Written by: Arzi gul Inspected by: Yanwei li Approved by: Sei even zhu
Date: 2020-05-18 Date: 2020-05-18 Date: 2020-05-18



BEFITLAB TEST TECHNOLOGY SHANGHAI CO., LTD.
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1、 Sample List

Manufacturer	Sample Name	Specification	Material	Lot
Wenzhou Meiyi Medical Device Co.,Ltd	3D FACIAL PROTECTIVE MASK(KN95 MASK)	MY-002	Spunbound polypropylene,melt blown polypropylene,	202004

2、 Sample Photos



Appendix 1: Visual inspection

1.1. Visual inspection: The visual inspection shall include the marking and information supplied by the manufacturer.

1.2. Result: Not tested

1.3. Note: As requested by the client, marking and information supplied by the manufacturer was not inspected.

Appendix 2: Package

2.1. Package: Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

2.2. Result: Pass

2.3. Note: In accordance with the requirement.

Appendix 3: Material

3.1. Material: Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

3.2. Result: Pass

3.3. Note: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

Appendix 4: Cleaning and disinfecting

4.1. Cleaning and disinfecting: If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

4.2. Result: N/A

4.3. Note: Single shift use only.

Appendix 5: Practical performance

5.1. Practical performance: The particle filtering half mask shall undergo practical performance tests under realistic conditions.
5.2. Result: Pass
5.3. Note: No imperfections.

Appendix 6: Finish of parts

6.1. Finish of parts: Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.
6.2. Result: Pass
6.3. Note: No sharp edges or burrs.

Appendix 7: Total inward leakage

7.1. Total inward leakage: For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22% for FFP1, 8% for FFP2, 2% for FFP3								
7.2. Result: Pass								
7.3. Note:								
Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Wu	1	A.R.	7.12	7.51	7.12	7.77	7.48	7.40
Li	2	A.R.	7.39	7.45	7.67	7.59	7.72	7.56
Zhang	3	A.R.	7.43	7.60	7.74	7.38	7.50	7.53
Xie	4	A.R.	7.15	7.50	7.03	7.31	7.08	7.21
Yang	5	A.R.	7.20	7.78	7.05	7.28	7.72	7.41
Lang	6	T.C.	7.02	7.68	7.50	7.49	7.72	7.48
Wang	7	T.C.	7.27	7.44	7.01	7.45	7.43	7.32
Yu	8	T.C.	7.77	7.76	7.56	7.08	7.73	7.58
Zhu	9	T.C.	7.01	7.07	7.13	7.34	7.26	7.16
Liu	10	T.C.	7.63	7.68	7.60	7.14	7.77	7.56
50 out of the 50 individual exercise results \leq 11 %					Pass			
10 of the 10 individual arithmetic means \leq 8 %								

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Subject	Face length	Face Width	Face Depth	Mouth Width
Wu	123	150	115	53
Li	128	133	109	48
Zhang	115	146	113	55
Xie	119	141	118	58
Yang	109	126	109	51
Lang	113	132	116	54
Wang	116	129	123	52
Yu	120	125	115	58
Zhu	119	146	120	53
Liu	108	120	113	51

Appendix 8: Penetration of filter material

8.1. Penetration of filter material: The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

8.2.Result: Pass

8.3. Note:

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	2.45	
		12	2.53	
		13	2.52	
	Simulated wearing treatment	14	2.56	
		15	2.53	
		16	2.57	
	Mechanical strength+ Temperature conditioned	17	2.54	
		18	2.56	
		19	2.58	

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Paraffin oil test	As received	20	4.15
		21	4.21
		22	4.19
	Simulated wearing treatment	23	4.25
		24	4.23
		25	4.26
	Mechanical strength+ Temperature conditioned	26	4.31
		27	4.29
		28	4.28
	Flow conditioning: Single filter: 95.0 L/min		

Appendix 9: Compatibility with skin

9.1. Compatibility with skin: Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

9.2. Result: Pass

9.3. Note: No irritation or any other adverse effect to health.

Appendix 10: Flammability

10.1. Flammability: When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

10.2. Result: Pass

10.3. Note:

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2s	Pass
	30	Burn for 1s	
Temperature conditioned	31	Burn for 1s	
	32	Burn for 1s	

Appendix 11: Carbon dioxide content of the inhalation air

11.1. Carbon dioxide content of the inhalation air: The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

11.2. Result: Pass

11.3. Note:

Condition	Sample No.	Result		Assessment
As received	33	0.3%	Mean value 0.3%	Pass
	34	0.3%		
	35	0.2%		

Appendix 12: Head harness

12.1. Head harness: The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

12.2. Result: Pass

12.3. Note: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

Appendix 13: Field of vision

13.1. Field of vision: The field of vision is acceptable if determined so in practical performance tests.

13.2. Result: Pass

13.3. Note: Pass the practical performance tests.

Appendix 14: Exhalation valve

14.1. Exhalation valve: A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

14.2. Result: N/A

14.3. Note: No exhalation valve.

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Appendix 15: Breathing resistance

15.1. Breathing resistance: The breathing resistance apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

15.2. Result: Pass

15.3. Note:

	Flow rate	36					37					38					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
As received	Inhalation	30 l/min	0.4	0.3	0.4	0.3	0.4	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.4	0.4	0.4
		95 l/min	1.4	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.4	1.3	1.4	1.4	1.4	1.4	1.3
	Exhalation	160 l/min	1.8	1.8	1.9	1.8	1.8	1.8	1.9	1.9	1.8	1.8	1.9	1.8	1.9	1.9	1.9
Simulated wearing treatment	Inhalation	30 l/min	0.3	0.3	0.3	0.4	0.3	0.3	0.4	0.3	0.4	0.3	0.3	0.3	0.4	0.3	0.4
		95 l/min	1.4	1.3	1.4	1.4	1.3	1.4	1.4	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.3
	Exhalation	160 l/min	1.9	1.8	1.8	1.9	1.8	1.9	1.8	1.8	1.8	1.9	1.8	1.8	1.9	1.8	1.8
Temperature conditioned	Inhalation	30 l/min	0.4	0.4	0.3	0.3	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3
		95 l/min	1.4	1.4	1.3	1.4	1.3	1.3	1.3	1.4	1.3	1.4	1.3	1.3	1.3	1.3	1.3
	Exhalation	160 l/min	1.8	1.9	1.9	1.8	1.9	1.8	1.9	1.8	1.9	1.9	1.8	1.9	1.8	1.8	1.9
Flow conditioned	Inhalation	30 l/min	0.3	0.4	0.3	0.4	0.3	0.3	0.3	0.4	0.4	0.3	0.3	0.3	0.4	0.4	0.3
		95 l/min	1.3	1.4	1.3	1.4	1.4	1.4	1.3	1.3	1.3	1.4	1.3	1.4	1.4	1.4	1.3
	Exhalation	160 l/min	1.9	1.8	1.9	1.9	1.9	1.9	1.9	1.8	1.9	1.9	1.9	1.9	1.8	1.9	1.8
Assessment	Pass																

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

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Appendix 16: Clogging

16.1. Clogging: For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory.

16.1.1 Breathing resistance: Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

16.1.2 Penetration of filter material: The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

16.2. Result: N/A

16.3. Note: Single shift use only.

Appendix 17: Demountable parts

17.1. Demountable parts: All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

17.2. Result: N/A

17.3. Note: No demountable parts.

***** 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.
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.
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