

Test Report

Applicant: Baoding Yinhong Yuhe medical device manufacturing Co., Ltd
Address: Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding ,
Hebei, China

The following sample(s) was/were submitted and identified on behalf of the client as:

Product name: Filtering half mask
Model: YH/9901
Trade mark: YINHONYUHE
Manufacturer: Baoding Yinhong Yuhe medical device manufacturing Co., Ltd
Address: Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding ,
Hebei, China
Classification: FFP2 NR
Sample quantity: 150 Pcs

Sample Received Date: Mar. 02, 2021
Testing Period: Mar. 02, 2021~ Mar. 09, 2021

Test Requirement:

According to the requirement of the client, the test item(s) of the sample is according to the standard EN 149:2001+A1:2009.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by: _____

Reviewed by: _____

Approved by: _____

Date: _____

2021-03-09

Summary of assessment*

Clause	Assessment
7.3 Visual inspection	NRq
7.4 Packaging	Pass
7.5 Material	Pass
7.6 Cleaning and disinfecting	N.A.
7.7 Practical performance	Pass
7.8 Finish of parts	Pass
7.9.1 Total inward leakage	Pass
7.9.2 Penetration of filter material	Pass
7.10 Compatibility with skin	Pass
7.11 Flammability	Pass
7.12 Carbon dioxide content of the inhalation air	Pass
7.13 Head harness	Pass
7.14 Field of vision	Pass
7.15 Exhalation valve(s)	N.A.
7.16 Breathing resistance	Pass
7.17 Clogging	N.A.
7.18 Demountable parts	N.A.

Key

Pass	Requirement satisfied.
NRq	The clauses were not required.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
N.A.	Requirement not applicable.

Test	Uncertainty
Total inward leakage	6.40 %
Penetration of filter material (NaCl)	1.60 %
Penetration of filter material (Paraffin Oil)	1.78 %
Carbon dioxide content of the inhalation air	5.34 %
Breathing resistance (30 L/min)	3.60 %
Breathing resistance (95 L/min)	2.20 %
Breathing resistance (160 L/min)	2.00 %

* Assessment relates only to those specimens which were tested and subjects in this report.

Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking
(EN 149:2001+A1:2009)

Clause 7.3 Visual inspection

Test Requirement	Results	Comment
Marking and the information supplied by the manufacturer, requirements refer to clause 9 and clause 10.	The clauses were not required.	NRq

Clause 7.4 Packaging

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

Clause 7.5 Material

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
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.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	Pass
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	Pass

Clause 7.6 Cleaning and Disinfecting

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
<p>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.</p> <p>With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.</p>	<p>Not applicable (Not designed to be re-usable)</p>	<p>N.A.</p>

Clause 7.7 Practical Performance

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
	Sample 11#~12#:	
<p>General:</p> <p>a) head harness comfort</p> <p>b) security of fastenings</p> <p>c) field of vision</p> <p>d) any other comments reported by the wearer on request.</p>	<p>No imperfections</p>	<p>Pass</p>
<p>Walking Test:</p> <p>The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.</p>	<p>No imperfections</p>	
<p>Work Simulation Test:</p> <p>a) walking on the level with headroom of (1.3 ± 0.2)m for 5min</p> <p>b) crawling on the level with headroom of (0.7 ± 0.05)m for 5min</p> <p>c) filling a small basket (see Figure 1, approximate volume = 8 L) with chippings or other suitable material from a hopper which stands 1.5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned.</p>	<p>No imperfections</p>	

Clause 7.8 Finish of Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage

(EN 149:2001+A1:2009 Clause 8.5)

Test Requirement	Results	Comment
<p>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:</p> <p style="padding-left: 40px;">25% for FFP1 11% for FFP2 5% for FFP3</p> <p>and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than:</p> <p style="padding-left: 40px;">22% for FFP1 8% for FFP2 2% for FFP3</p>	Detail refer to Appendix 1	Pass

Appendix 1: Summarization of Test Data

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)
Huang	1#	A.R.	6.6	6.7	6.8	6.9	6.7	6.74
Zhou	2#	A.R.	4.2	4.3	4.4	4.6	4.3	4.36
Ma	3#	A.R.	5.8	5.9	6.1	6.2	5.7	5.94
Wu	4#	A.R.	7.3	7.4	7.6	7.7	7.4	7.48
Li	5#	A.R.	7.7	7.8	7.9	8.0	7.6	7.80
Wu	6#	T.C.	6.2	6.3	6.6	6.7	6.3	6.42
Zhai	7#	T.C.	6.5	6.6	6.7	6.9	6.4	6.62
Zheng	8#	T.C.	7.1	7.2	7.4	7.5	7.2	7.28
Huang	9#	T.C.	5.4	5.6	5.7	5.8	5.3	5.56
Wu	10#	T.C.	6.3	6.4	6.6	6.7	6.4	6.48

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Huang	130	140	125	53
Zhou	100	148	125	55
Ma	120	158	110	50
Wu	110	148	121	44
Li	112	146	112	50
Wu	120	154	128	54
Zhai	135	165	125	53
Zheng	106	155	112	54
Huang	105	157	118	51
Wu	112	172	118	55

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11)

Test Requirement			Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Appendix 2	Pass
Classification	Maximum penetration of test aerosol(%)			
	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			Average in 30s after 3 min	Max. during exposure	
Sodium chloride test	A.R.	13#	0.73	/	Pass
		14#	0.74	/	
		15#	0.73	/	
	S.W.	19#	0.73	/	
		20#	0.73	/	
		21#	0.73	/	
	M.S. + T.C.	25#	/	0.75	
		26#	/	0.74	
		27#	/	0.73	
Paraffin oil test	A.R.	16#	0.64	/	
		17#	0.66	/	
		18#	0.63	/	
	S.W.	22#	0.66	/	
		23#	0.62	/	
		24#	0.62	/	
	M.S. + T.C.	28#	/	1.88	
		29#	/	1.86	
		30#	/	1.29	
Flow rate of test aerosol: 95.0 L/min					

Clause 7.10 Compatibility with Skin

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health.	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature when tested, the particle filtering half mask shall not burn or not to continue on burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	Assessment
A.R.	31#	Flammable, burn for no more than 5 s	Pass
	32#	Nonflammable	
T.C.	33#	Flammable, burn for no more than 5 s	
	34#	Nonflammable	

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result	Assessment
A.R.	35#	0.50%	Pass
	36#	0.50%	
	37#	0.50%	
		Mean value: 0.50%	

Clause 7.13 Head Harness

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
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.	Comply	

Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance.	Comply	Pass

Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No valves.	N.A.
b) 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.	No valves.	
c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300L/min over a period of 30 s.	No valves.	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	No valves.	

Clause 7.16 Breathing Resistance

EN 149:2001+A1:2009, Clause 8.9)

Test Requirement				Results	Comment
The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements as the following table.				Detail refer to Appendix 5	Pass
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		

Appendix 5: Summarization of Test Data

Specimen	Condition	Inhalation(mbar)		Exhalation resistance(mbar)				
		At 30 L/min	At 95 L/min	At 160 L/min				
				A	B	C	D	E
38#	A.R.	0.43	1.44	2.30	2.29	2.30	2.29	2.28
39#		0.44	1.44	2.31	2.31	2.30	2.30	2.29
40#		0.43	1.43	2.30	2.30	2.29	2.28	2.27
41#	S.W.	0.44	1.43	2.31	2.31	2.31	2.30	2.29
42#		0.44	1.44	2.31	2.30	2.30	2.30	2.30
43#		0.45	1.45	2.32	2.31	2.32	2.31	2.30
44#	T.C.	0.39	1.35	2.20	2.20	2.19	2.19	2.18
45#		0.39	1.36	2.21	2.20	2.21	2.20	2.19
46#		0.38	1.35	2.21	2.20	2.21	2.20	2.19
/	F.C.	/	/	/	/	/	/	/
/		/	/	/	/	/	/	/
/		/	/	/	/	/	/	/

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

Clause 7.17 Clogging

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment																		
<p>Clause 7.17.2 Breathing resistance</p> <p>Valved particle filtering half masks:</p> <p>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.</p> <p>Valveless particle filtering half masks:</p> <p>After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow.</p>	Requirement not applicable.	N.A.																		
Test Requirement	Results	Comment																		
<p>Clause 7.17.3 Penetration of filter material</p> <p>All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.</p> <table border="1" data-bbox="164 1137 924 1480"> <thead> <tr> <th rowspan="4">Classification</th> <th colspan="2">Maximum penetration of test aerosol</th> </tr> <tr> <th>Sodium chloride test 95 L/min</th> <th>Paraffin oil test 95 L/min</th> </tr> <tr> <th>%</th> <th>%</th> </tr> <tr> <th>max.</th> <th>max.</th> </tr> </thead> <tbody> <tr> <td>FFP1</td> <td>20</td> <td>20</td> </tr> <tr> <td>FFP2</td> <td>6</td> <td>6</td> </tr> <tr> <td>FFP3</td> <td>1</td> <td>1</td> </tr> </tbody> </table>	Classification	Maximum penetration of test aerosol		Sodium chloride test 95 L/min	Paraffin oil test 95 L/min	%	%	max.	max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Requirement not applicable.	N.A.
Classification		Maximum penetration of test aerosol																		
		Sodium chloride test 95 L/min	Paraffin oil test 95 L/min																	
		%	%																	
	max.	max.																		
FFP1	20	20																		
FFP2	6	6																		
FFP3	1	1																		

Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No detachable part	N.A.

Sample photo(s):



Fig.1



Fig.2

****End of Report****

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