





中国认可 国际互认 检测 TESTING CNAS L0599

Test Report SL52025269550701TX Date:June 23 2020

Page 1 of 9

ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD NO.668 CHANHUA ROAD FOTANG TOWN INDUSTRIAL FUNCTIONAL AREA 322002 YIWU CITY, ZHEJIANG PROVINCE PEOPLE'S REPUBLIC OF CHINA

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

Sample Description : (A) Protective mask

Style No. : Cup type

Composition : (A)60% Nonwoven, 40% Melt-blown fabric

Sample Color : (A)White

Manufacturer : ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD

Country of Destination : Europe

Supplier : ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 04, 2020

Testing Period : Jun 04, 2020 - Jun 23 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the

sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center





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SL52025269550701TX

Date: June 23 2020

Page 2 of 9

Test Result

Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

EN 149:2001+A1:2009

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	Comply	Pass
before use.		

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	
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	
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	

Clause 7.6 Cleaning and Disinfecting

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

Test Requirement	Results	Comment
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. 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.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance

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

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass



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SL52025269550701TX

Date: June 23 2020

Page 3 of 9

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
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. 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	Detail refer to Appendix 1	Meet FFP1, Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

inward Le	eakage res	<u>l Dala</u>						
Subject	Sample	Condition	Walk(%)	Head	Head	Talk(%)	Walk(%)	Mean(%)
-	No.			Side/side(%)	up/down(%)			
Zhou	1	A.R.	6.83	4.58	5.61	5.14	3.69	5.17
Luo	2	A.R.	5.23	7.16	5.94	7.21	5.25	6.16
Lu	3	A.R.	6.10	4.98	4.97	5.90	5.67	5.52
Wang	4	A.R.	5.37	4.42	4.40	4.88	3.53	4.52
Bao	5	A.R.	5.63	6.33	6.42	7.18	5.51	6.21
Ding	6	T.C.	4.86	3.74	5.50	3.54	5.94	4.72
Li	7	T.C.	5.81	6.29	7.19	6.37	7.09	6.55
Chen	8	T.C.	5.00	6.72	3.37	4.16	5.20	4.89
Song	9	T.C.	5.50	6.66	6.25	4.72	6.62	5.95
Ye	10	T.C.	7.90	6.10	6.29	7.45	6.66	6.88

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50
Ding	134	150	110	52



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Test Re	port SL52)25269550701TX	Date:June 23 202	20 Page 4 of 9
Liu	120	135	117	50
Ye	126	137	105	52

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

	Test Requirement				Results	Comment
		of the filter of the particle filte	the			
requ	uirements of t	the following table.				
	Classifica	Maximum penetration	on of test aerosol			
	tion	Sodium chloride test 95	Paraffin oil test 95 l/min			
		l/min			Detail refer to	Meet FFP1,
		%	%		Appendix 2	Meet FFP2
		max.	max.			
	FFP1	20	20			
	FFP2	6	6			
	FFP3	1	1			

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
		1	1.215
	As received	2	1.388
		3	1.231
		4	1.285
Sodium chloride test	Simulated wearing treatment	5	1.297
		6	1.364
	Machanical strangth (Tomporature	7	1.679
	Mechanical strength +Temperature conditioned	8	1.827
	conditioned	9	1.729
		10	1.657
	As received	11	1.724
		12	1.836
		13	1.659
Paraffin oil test	Simulated wearing treatment	14	1.724
		15	1.694
	Mochanical strongth a Tomporature	16	2.367
	Mechanical strength +Temperature conditioned	17	2.474
	Conditioned	18	2.674



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SL52025269550701TX

Date:June 23 2020

Page 5 of 9

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	Detail refer to	Door
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.	Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
	1	NIL
As received	2	NIL
	3	NIL
Temperature conditioned	4	NIL

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.	Resu	Result(%)				
		0.4654					
	1						
As resolved		0.4643	Moon value 0.46				
As received	2		Mean value:0.46				
		0.4639]				
	3						



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SL52025269550701TX

Date: June 23 2020

Page 6 of 9

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	
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	Pass

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
tests.		1 466

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.	Not applicable due to No exhalation valve	
(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.	Not applicable due to No exhalation valve	N.A.
(c) 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.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	



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SL52025269550701TX

Date:June 23 2020

Page 7 of 9

Clause 7.16 Breathing Resistance

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

	Test	Results	Comment			
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.						
Classification	Maximu	um permitted resista	ance (mbar)		Datail safasta	Meet FFP1,
	Inf	nalation	Exhalation		Detail refer to	Meet FFP2,
	30 l/min	95 l/min	160 l/min		Appendix 5	Meet FFP3
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

Breathing resistance (mbar)

ī																	
					1			2				3					
	Flow rate(I/	min)	Α	В	C	D	ш	Α	В	C	D	Е	Α	В	C	D	Ε
As received	Inhalation	30	0.3	0.4	0.3	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.3	0.4	0.4	0.5	0.4
	IIIIaiation	95	1.0	1.2	1.1	1.1	1.0	1.2	1.0	1.2	1.1	1.0	1.2	1.1	1.2	1.1	1.2
	Exhalation	160	2.5	2.6	2.5	2.5	2.6	2.5	2.6	2.6	2.5	2.5	2.6	2.5	2.6	2.5	2.5
	= , , , , , ,		4 5							6							
Simulated	Flow rate(I/	min)	Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
wearing	Inhalation	30	0.4	0.5	0.4	0.4	0.5	0.5	0.4	0.4	0.5	0.5	0.4	0.4	0.5	0.5	0.4
treatment	IIIIaiation	95	1.1	1.3	1.2	1.2	1.1	1.3	1.1	1.3	1.1	1.3	1.1	1.3	1.1	1.3	1.2
	Exhalation	160	2.6	2.7	2.6	2.6	2.7	2.6	2.7	2.6	2.6	2.7	2.6	2.7	2.7	2.7	2.6
	7 8								9								
	Flow rate(I/	min)	Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
Temperature conditioned	Inhalation	30	0.3	0.3	0.4	0.3	0.3	0.3	0.4	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.4
	IIIIIaiallON	95	1.0	1.2	1.1	1.0	1.1	1.0	1.2	1.1	1.0	1.2	1.1	1.0	1.2	1.1	1.2
	Exhalation	160	2.4	2.3	2.4	2.4	2.5	2.5	2.4	2.4	2.5	2.4	2.4	2.5	2.4	2.5	2.4

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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SL52025269550701TX

Date: June 23 2020

Page 8 of 9

Clause 7.17 Clogging

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

	Test Requirement	Results	Comment
Valved particle fil After clogging the FFP1: 4 mbar, FI The exhalation re flow. Valveless particle After clogging the	eathing resistance tering half masks: e inhalation resistances shall not FP2: 5 mbar, FFP3: 7 mbar at 95 esistance shall not exceed 3 mb e filtering half masks: e inhalation and exhalation resis FP2: 4 mbar, FFP3: 5 mbar at 95	Optional for single shift device only	N.A.
All types (valved	enetration of filter material I and valveless) of particle filter g requirement shall also meet th Maximum penetration Sodium chloride test 95 l/min % max. 20 6 1	Optional for single shift device only	N.A.

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,	No demountable	N.A.
where possible by hand	parts	IV.A.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%



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SL52025269550701TX

Date:June 23 2020

Page 9 of 9

Sample Photo



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