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 Request Age Grading: 2 years
SGS Internal Ref No.	:	SHHL2006525455MD
Style No.	:	folding type, 1117
Sample Color	:	(A)WHITE
Manufacturer	:	ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD
Country of Origin	:	China
Supplier	:	ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 06, 2020
Testing Period	:	Jul 06, 2020 - Jul 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

Sara Guo (Account Executive)

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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 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	
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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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

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	7.11	7.23	5.02	5.04	6.86	6.25
Luo	2	A.R.	6.70	7.20	6.98	6.40	7.72	7.00
Lu	3	A.R.	6.95	7.32	5.36	5.97	5.55	6.23
Wang	4	A.R.	6.02	5.75	4.94	5.56	4.98	5.45
Bao	5	A.R.	8.02	6.39	7.11	5.98	7.71	7.04
Ding	6	T.C.	7.37	5.21	5.55	4.54	4.96	5.53
Li	7	T.C.	6.17	7.65	7.69	8.15	7.13	7.36
Chen	8	T.C.	5.36	5.12	4.80	6.44	5.79	5.50
Song	9	T.C.	4.82	7.13	6.91	5.56	7.09	6.30
Ye	10	T.C.	5.98	8.24	7.60	6.87	7.79	7.30

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

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Ding	134	150	110	52
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
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Meet FFP1, Meet FFP2

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % 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 (%)
Sodium chloride test	As received	1	0.637
		2	0.456
		3	0.523
	Simulated wearing treatment	4	0.467
		5	0.564
		6	0.574
	Mechanical strength +Temperature conditioned	7	0.852
		8	0.681
		9	0.778
Paraffin oil test	As received	10	1.247
		11	1.426
		12	1.368
	Simulated wearing treatment	13	1.372
		14	1.270
		15	1.359
	Mechanical strength +Temperature conditioned	16	4.067
		17	4.327
		18	3.964
Flow conditioning：Single filter: 95.0 L/min			

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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 to 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
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	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.	Result(%)	
As received	1	0.4774	Mean value:0.48
	2	0.4782	
	3	0.4768	

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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 tests.	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.	Not applicable due to No exhalation valve	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.	Not applicable due to No exhalation valve	
(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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Clause 7.16 Breathing Resistance
(EN 149:2001+A1:2009, Clause 8.9)

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 5	Meet FFP1, Meet FFP2, Meet FFP3

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

Breathing resistance (mbar)

	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30	0.2	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3
		95	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.7	0.8	0.7	0.8
	Exhalation	160	2.0	2.1	2.2	2.0	2.1	2.1	2.0	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.1
Simulated wearing treatment	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.3	0.3	0.3	0.2	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.2
		95	0.8	0.9	0.8	0.9	0.8	0.9	0.9	0.8	0.8	0.9	0.9	0.8	0.9	0.9	0.8
	Exhalation	160	2.1	2.0	2.0	2.0	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.0	2.0	2.1	2.0
Temperature conditioned	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.2	0.3	0.2	0.3	0.3	0.2	0.2	0.3
		95	0.8	0.7	0.8	0.7	0.7	0.8	0.7	0.7	0.8	0.8	0.7	0.7	0.8	0.8	0.7
	Exhalation	160	1.9	2.0	1.9	2.0	2.0	1.9	1.9	2.0	1.9	2.0	1.9	2.0	1.9	1.9	2.0

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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Clause 7.17 Clogging
(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment
Clause 7.17.2 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	Optional for single shift device only	N.A.
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Optional for single shift device only	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 demountable parts	N.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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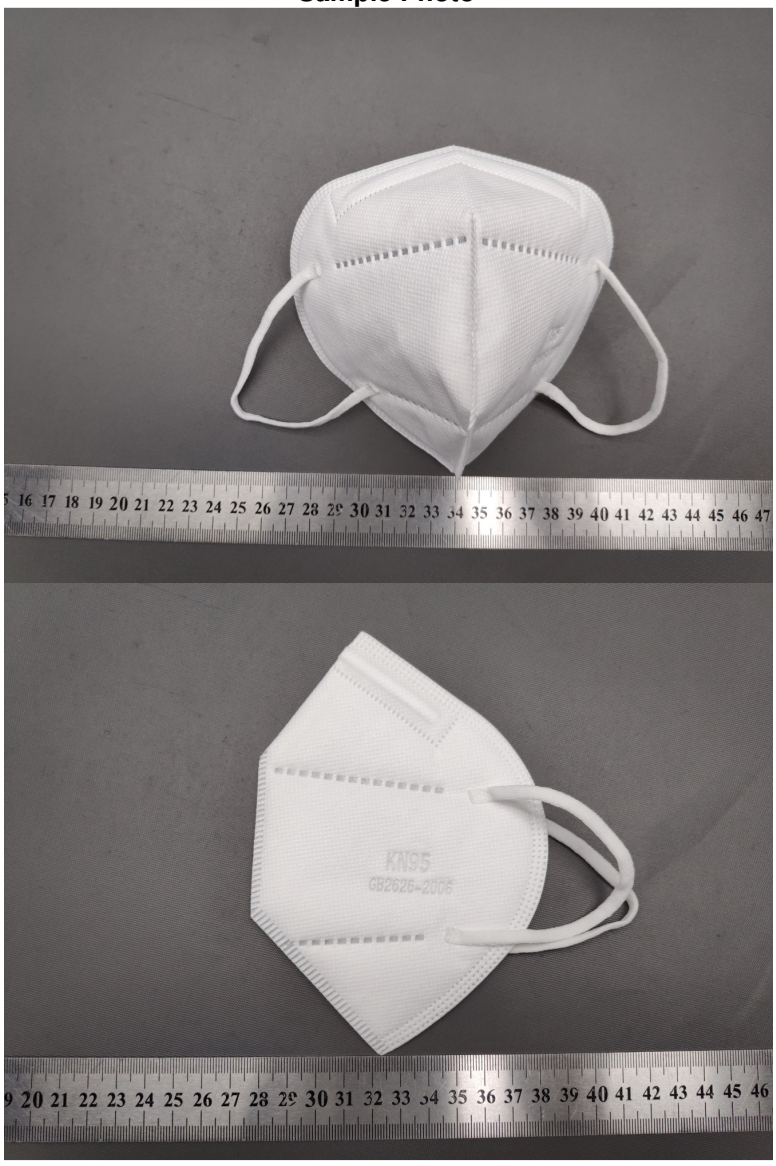
Sample Photo



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