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Test Report SL52105221541801TX Date:February 03,2021

ZHANGJIAGANG SHENGANG MEDICAL PRODUCTS CO.,LTD.

XICAN VILLAGE, FENGHUANG TOWN, ZHANGJIAGANG CITY, JIANGSU PROVINCE

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

Sample Description : (A)Filtering Half Mask

Sample Color : (A)white

Composition : (A)PP nonwoven, Melt-blown fabric, Hot air cotton

Style No. : M2004 Retest : No

Sample Size : 15.5cmx10.5cm

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

Sample Receiving Date : Jan 25, 2021

Testing Period : Jan 25, 2021 - Feb 03, 2021

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

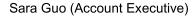
sample(s) tested, for further details, please refer to the following page(s).

#### 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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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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#### Clause 7.8 Finish of Parts

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

· ·	esults	Comment
	arp edges 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 valve leakage (if exhalation valve 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

IIIWalu Le	takaye res	<u>i Dala</u>						
Subject	Sample	Condition	Walk(%)	Head	Head	Talk(%)	Walk(%)	Mean(%)
	No.			Side/side(%)	up/down(%)			
Zhou	1	A.R.	3.04	3.36	3.09	3.05	3.99	3.31
Luo	2	A.R.	4.23	4.76	3.75	4.59	4.07	4.28
Lu	3	A.R.	3.40	3.10	3.93	3.23	3.54	3.44
Wang	4	A.R.	2.03	1.88	2.78	2.35	2.43	2.29
Bao	5	A.R.	4.48	4.29	4.85	4.45	3.17	4.25
Ding	6	T.C.	2.08	2.10	2.73	2.89	2.97	2.55
Li	7	T.C.	4.31	5.31	4.18	4.46	4.80	4.61
Chen	8	T.C.	2.23	2.75	2.70	3.39	2.12	2.64
Song	9	T.C.	3.83	3.29	3.64	3.25	3.85	3.57
Ye	10	T.C.	4.53	4.32	4.63	5.56	4.56	4.72

#### **Facial Dimension**

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	Resul	ts	Comment	
		of the filter of the particle filter	Э			
requ	urements of t	the following table.				
	Classifica	Maximum penetration				
	tion	Sodium chloride test 95	Paraffin oil test 95 l/min			
		l/min		Detail ref	er to	Meet FFP1,
		%	%	Append	ix 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	0.373			
	As received	2	0.309			
		3	0.356			
		4	0.345			
Sodium chloride test	Simulated wearing treatment	5	0.325			
		6	0.319			
	NAb	7	1.815			
	Mechanical strength +Temperature conditioned	8	1.596			
	conditioned	9	1.675			
		10	0.193			
	As received	11	0.270			
		12	0.195			
		13	0.196			
Paraffin oil test	Simulated wearing treatment	14	0.226			
	-	15	0.234			
	<b>M</b> 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	16	1.030			
	Mechanical strength +Temperature	17	1.605			
	conditioned	18	1.947			
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	Detail refer to	Pass
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	F d 5 5

## **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	Detail refer to	Pass
exceed an average of 1,0 % (by volume)	Appendix 4	F488

# **Appendix 4: Summarization of Test Data**

## Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result				
	1	0.5611				
As received	2	0.5635	Mean value:0.56			
	3	0.5641				



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

## 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.	Comply	F 488

## 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	N.A
(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)

	Tes	Results	Comment			
		y to valved and val requirements of the		ing		
Classification	Maximu	um permitted resista	ance (mbar)		Detellerite	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)

					1					2					3		
	Flow rate(l	min)	Α	В	C	D	Е	Α	В	C	D	Е	Α	В	C	D	Е
As received	Inhalation	30	0.5	0.5	0.4	0.5	0.4	0.5	0.5	0.5	0.4	0.5	0.4	0.5	0.5	0.5	0.5
	Inhalation	95	1.8	1.8	1.8	1.8	1.7	1.7	1.7	1.8	1.7	1.8	1.8	1.8	1.8	1.8	1.8
	Exhalation	160	2.6	2.7	2.7	2.7	2.6	2.6	2.7	2.6	2.7	2.7	2.7	2.7	2.7	2.7	2.6
	E			4 5					6								
Simulated	Flow rate(l	min)	Α	В	С	D	Ε	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	0.5	0.4	0.4	0.5	0.4	0.5	0.5	0.5	0.4
treatment	IIIIIaiatioii	95	1.8	1.7	1.8	1.8	1.8	1.7	1.7	1.7	1.8	1.7	1.8	1.7	1.7	1.8	1.8
	Exhalation	160	2.7	2.6	2.7	2.7	2.6	2.7	2.7	2.6	2.6	2.6	2.6	2.7	2.7	2.6	2.7
	<b>F</b> I /I.	/ · - \			7			8					9				
	Flow rate(l	min)	Α	В	С	ם	Ш	Α	В	C	D	Е	Α	В	C	D	Е
Temperature	Inhalation	30	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.4	0.4	0.4	0.5	0.4	0.5	0.5	0.4
conditioned	IIIIIaialiOII	95	1.8	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.7	1.7	1.8	1.7	1.8	1.7
	Exhalation	160	2.6	2.6	2.7	2.6	2.6	2.6	2.6	2.6	2.7	2.7	2.6	2.7	2.6	2.6	2.7

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)

FFP1: 4 mbar, FFP2: The exhalation resists flow.  Valveless particle filte After clogging the inhibit FFP1: 3 mbar, FFP2:  Clause 7.17.3 Penetro	ng half masks: halation resistances shall not the shall not exceed 3 mb ering half masks: halation and exhalation resist the shar, FFP3: 5 mbar at 95	SL/min continuous flow ar at 160 L/min continuous tances shall not exceed:	Optional for single shift device only	N.A.
After clogging the inharmonic FFP1: 3 mbar, FFP2:  Clause 7.17.3 Penetra	halation and exhalation resist :: 4 mbar, FFP3: 5 mbar at 95			
	ration of filter material			
meet the clogging req	nd valveless) of particle filter equirement shall also meet the	e requirements.		
Classificatio	Maximum penetration			
n So	odium chloride test 95 l/min	Paraffin oil test 95 l/min	Optional for single	N.A.
	%	%	shift device only	
	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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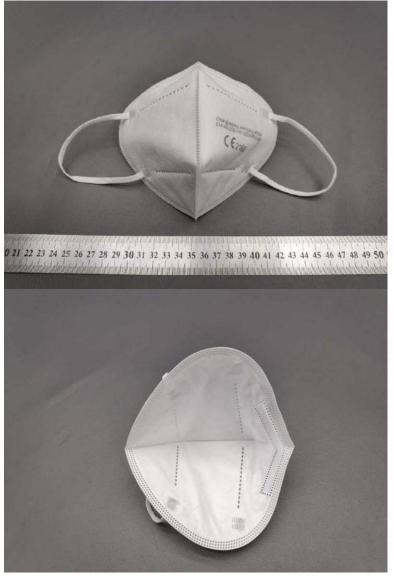


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# Sample Photo





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\*\*\*End of Report\*\*\*



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