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TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product:	**Particle filtering half mask**
Report No:	**2024 (D) – 019**
Client:	**SPRO Medical Products (Xiamen) Co., Ltd.**
Model (s):	**GL001A**
Date of sample received:	**2024.02.18**
Date(s) of tests:	**2024.02.19 – 2024.03.12**

DESCRIPTION OF SAMPLES

General Information	**Classification**	**Main Components**
	FFP2 NR	White folding mask
Manufacturer	SPRO Medical Products (Xiamen) Co., Ltd.	
Manufacturer Address	2nd Floor of No. 9 Fangqian Building, No. 358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China	

Signed: 陈倬为

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Issued: 2024.03.12

Conditions:

The test results presented in this report relate to the samples tested only.

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Test Results

7.3 Visual inspection **Pass[1]**

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

Note1: In accordance with the requirement.

7.4 Package **Pass[2]**

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.

Note2: In accordance with the requirement.

7.5 Material **Pass[3]**

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.

Note3: 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.

7.6 Cleaning and disinfecting **N/A[4]**

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.

Note4: Single shift use only.

7.7 Practical performance **Pass[5]**

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note5: No imperfections.

7.8 Finish of parts **Pass[6]**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage **Pass[7]**

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

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material **Pass[8]**

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%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin **Pass[9]**

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.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability **Pass[10]**

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.

Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air **Pass[11]**

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

Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness **Pass[12]**

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.

Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision **Pass[13]**

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

Note13: Pass the practical performance tests.

7.15 Exhalation valve **N/A[14]**

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.

Note14: No exhalation valve.

7.16 Breathing resistance **Pass[15]**

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

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

7.17 Clogging **N/A[16]**

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

7.17.3 Penetration of filter material

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

Note16: Single shift use only.

7.18 Demountable parts **N/A [17]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand
Note17: No demountable parts.

9 Marking **Not tested**

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1
The name, trademark or other means of identification of the manufacturer or supplier.
9.1.2
Type-identifying marking.
9.1.3 Classification
The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
9.1.4
The number and year of publication of this European Standard.
9.1.5
At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.
9.1.6
The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.
9.1.7
The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.
9.1.8
The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1

The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2

Type-identifying marking.

9.2.3

The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5

If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6

Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149: 2001+A1: 2009 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Gong	1	A.R.	3.64	3.95	4.24	3.86	3.75	3.9
Yu	2	A.R.	4.32	4.74	4.89	4.54	4.69	4.6
Yuan	3	A.R.	5.42	5.43	5.95	5.71	5.77	5.7
Xu	4	A.R.	4.26	4.35	4.56	4.46	4.26	4.4
Gao	5	A.R.	3.74	4.24	4.47	3.99	3.78	4.0
Zhang	6	T.C.	5.44	5.68	5.87	5.76	5.48	5.6
Liu	7	T.C.	6.53	6.55	6.84	6.76	6.87	6.7
Zhi	8	T.C.	6.25	6.61	6.82	6.36	6.44	6.5
Fang	9	T.C.	7.42	7.60	7.85	7.51	7.74	7.6
Chen	10	T.C.	4.63	4.75	5.26	5.07	4.89	4.9
50 out of the 50 individual exercise results ≤11 % 10 out of the 10 individual arithmetic means ≤8 %							Pass	

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Gao	120	138	113	62
Gong	122	140	115	65
Yu	119	160	139	55
Yuan	112	132	115	61
Xu	110	130	118	60
Huang	114	117	108	57
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

Table -7.9.2 Penetration of filter material

Test specification: EN 149: 2001+A1: 2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	31	0.314	Pass
		32	0.487	
		33	0.338	
	Simulated wearing treatment	34	0.446	
		35	0.511	
		36	0.425	
	Mechanical strength+ Temperature conditioned	37	0.407	
		38	0.513	
		39	0.528	
Paraffin oil test	As received	40	1.32	
		41	1.55	
		42	1.79	
	Simulated wearing treatment	43	2.47	
		44	2.09	
		45	1.26	
	Mechanical strength+ Temperature conditioned	46	1.92	
		47	2.74	
		48	2.43	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149: 2001+A1: 2009 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	21	Didn't burn	Pass
	22	Didn't burn	
Temperature conditioned	23	Didn't burn	
	24	Didn't burn	

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149: 2001+A1: 2009 Clause 8.7

Condition	Sample No.	Result		Assessment
As received	25	0.42 %	Mean value 0.4 %	Pass
	26	0.44 %		
	27	0.41 %		

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149: 2001+A1: 2009 Clause 8.9

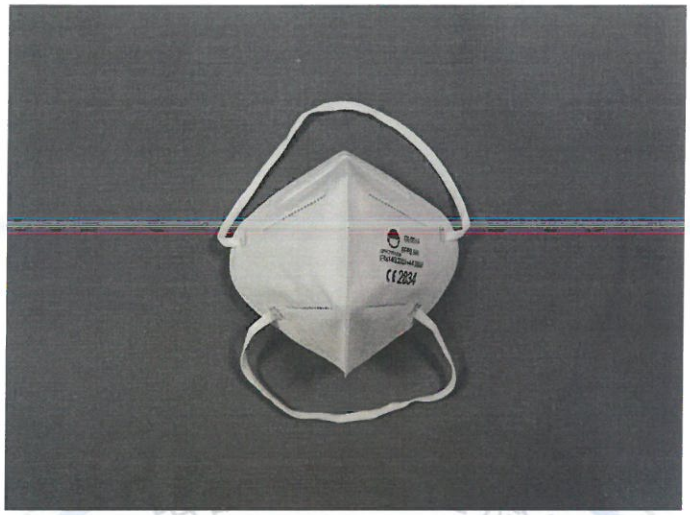
			16					17					18				
	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.4
		95 l/min	1.1	1.2	1.2	1.2	1.1	1.2	1.1	1.2	1.2	1.2	1.1	1.1	1.2	1.2	1.2
	Exhalation	160 l/min	1.8	1.9	1.9	1.8	1.9	1.8	1.9	1.8	1.9	1.9	1.8	1.9	1.8	1.9	1.8
			19					15					11				
Simulated wearing treatment	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.4
		95 l/min	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.1	1.2	1.2	1.1	1.2	1.2	1.2
	Exhalation	160 l/min	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.8	1.9	1.9	1.9
			12					13					14				
Temperature conditioned	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.4	0.5	0.5	0.4
		95 l/min	1.2	1.2	1.2	1.1	1.2	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
	Exhalation	160 l/min	1.9	1.8	1.9	1.9	1.9	1.8	1.9	1.9	1.9	1.8	1.8	1.9	1.9	1.9	1.9
Assessment	Pass																

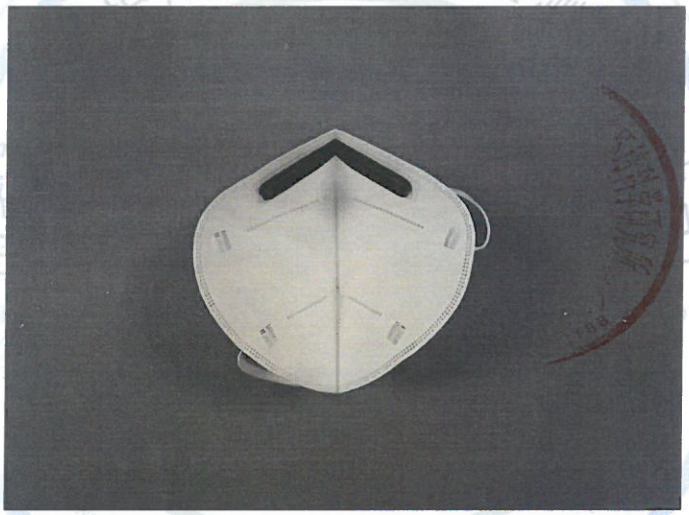
A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

Test	**Uncertainty**
Total inward leakage	4.1%
Penetration of filter material	1.1%
Flammability	5.0%
Carbon dioxide content of the inhalation air	2.6%
Breathing resistance	1.8%

End of Annex A

ANNEX B PHOTOS OF SAMPLES





End of Annex B