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TEST REPORT

EN 149:2001+A1:2009

Filtering half masks to protect against particles

Report no: WLH0093-2022
Product: Particle Filtering Half Mask
Model(s): GL005A
Main components: Mask body, without exhalation valve
Date(s) of tests: 18th Jul 2022 ~ 29th Jul 2022

Client

SPRO Medical Products (Xiamen) Co., Ltd.

West of 1st to 5th Floor, No. 139, Tong'an Garden,
Tong'an Industrial Area, Xiamen City, Fujian
Province, China

Client order: /

Order(s) received: Jul, 2022

Manufacturer

SPRO Medical Products (Xiamen) Co., Ltd.

2nd Floor of No.9 & D Building, No.358, Xilin Road,
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Contact: /

E-mail: /

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Conditions:

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Any objection should be submitted within 2 weeks from the date of receipt of the report, and it will not be accepted after the deadline.

Specimens will be disposed of 4 weeks from the date of this report, unless otherwise instructed.

Signed: 1/

张明明/Zhang Mingming, Authorized Signatory

Issued: 2022-08-02

Summary of assessment*

Clause		Assessment
Model:		GL005A
7.4	Packaging	NRq
7.5	Material	Pass
7.6	Cleaning and disinfecting	NAP
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: Sodium chloride	Pass
7.9.2	Penetration of filter material: Paraffin oil	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)	NAP
7.16	Breathing resistance	Pass
7.17	Clogging	NRq
7.18	Demountable parts	Pass
9	Marking	NRq
10	Information to be supplied by the manufacturer	NRq

Key

	Shading shows the clauses requested.
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "Result details" section for more information.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
NAs	Assessment not carried out.
NAP	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those specimens which were tested and are the subject of this report.

Product characteristics

Property	Characteristic
Model	GL005A
Classification claimed	FFP2 NR
Exhalation valve(s)	None

Submission details

Product	Quantity	Date received	Specimen No.
GL005A Particle Filtering Half Mask	60	18 th Jul 2022	WLH0093-2022 -01 to -60

Photographs of the products tested

SPRO Medical Products (Xiamen) Co., Ltd.'s Model GL005A Particle Filtering Half Mask



CASST specimen number WLH0093-2022-39

Procedures

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with EN 149:2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received.

Result details**7.4 Packaging****NRq**

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.

7.5 Material**Pass¹**

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.

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.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note1: In accordance with the requirement.

Specimens -14, -15, -16 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.

Specimens -01, -02, -03 were conditioned in accordance with 8.3.1 and 8.3.2, None of the specimens conditioned suffered collapse.

7.6 Cleaning and disinfecting**NAP²**

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.

Note2: Single shift use only.

7.7 Practical performance**Pass³**

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

Note3: No imperfections.

Specimen and subject details:

Specimen	Subject
-41	ZWQ
-42	JLX

7.8 Finish of parts**Pass⁴**

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

Note4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 Total inward leakage (%)**Pass⁵**

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.

Note5: All the 50 individual exercise results were not greater than 11%; all the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Subject	Specimen	Cond	Walk	Head side/side	Head up/down	Talk	Walk	Mean
ZWQ	-41	AR	1.3	1.6	1.4	0.5	1.0	1.2
JLX	-42	AR	1.1	1.5	1.4	1.7	1.1	1.3
MZH	-43	AR	2.7	3.7	3.5	2.9	2.8	3.1
ZH	-44	AR	1.7	1.8	2.0	1.6	1.7	1.7
CH	-45	AR	4.1	4.7	5.5	3.5	3.7	4.3
TJ	-04	TC	4.1	5.3	4.1	3.1	3.4	4.0
LCF	-05	TC	0.3	0.4	0.4	0.4	0.4	0.4
ZMM	-06	TC	0.9	1.2	1.3	1.0	0.8	1.0
JXQ	-07	TC	3.8	5.3	4.9	5.3	3.9	4.6
YZF	-08	TC	4.2	5.8	5.6	4.7	4.2	4.9
Maximum permitted			11					8

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
ZWQ	128	150	128	58
JLX	119	152	109	59
MZH	99	143	105	48
ZH	102	152	113	55
CH	111	135	108	48
TJ	105	151	110	52
LCF	119	165	121	56
ZMM	114	157	119	50
JXQ	101	137	91	54
YZF	113	151	106	48

7.9.2 Penetration of filter material

Pass

The penetration of the filter of the particle filtering half mask shall meet the requirements:

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

Sodium chloride test results: (Pass)

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-26	A.R.	0.04	
-27		0.04	
-28		0.05	
-14	S.W.	0.03	
-15		0.07	
-16		0.06	
-20	M.S. + T.C.	0.04	0.05
-21		0.09	0.12
-22		0.06	0.07
Maximum permitted		6	

Paraffin oil test results: (Pass)

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-29	A.R.	0.08	
-30		0.13	
-31		0.04	
-17	S.W.	0.04	
-18		0.04	
-19		0.05	
-23	M.S. + T.C.	0.15	0.30
-24		0.10	0.17
-25		0.14	0.28
Maximum permitted		6	

7.10 Compatibility with skin**Pass⁶**

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.

Note6: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability**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.

Specimen	Condition	Results
-32	A.R.	burn for 0.5 s
-33		burn for 0.6 s
-09	T.C.	burn for 0.6 s
-10		burn for 0.7 s

7.12 Carbon dioxide content of the inhalation air**Pass**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).

Specimen	CO ₂ (%)
-32	0.24
-33	0.21
-34	0.19
Maximum permitted	1.0

7.13 Head harness**Pass⁷**

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.

Note7: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. Head harness (ear straps with auxiliary hook) can be donned and removed easily, adjustable or self-adjusting, and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 Field of vision**Pass⁸**

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

Note8: Specimens -41 and -42 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve**NAP**

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.

7.16 Breathing resistance**Pass⁹**

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min×2.0 l/stroke)
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note9: FFP2 Filtering face mask. Test results are detailed below.

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)				
		At 30 l/min	At 95 l/min	Breathing machine (25 cycles/min×2.0 l/stroke)				
				A	B	C	D	E
-35	A.R.	0.27	0.89	1.77	1.78	1.76	1.81	1.83
-36		0.29	0.96	1.81	1.79	1.80	1.85	1.86
-37		0.29	0.96	1.81	1.83	1.80	1.86	1.87
-11	T.C.	0.25	0.88	1.71	1.72	1.67	1.69	1.74
-12		0.28	0.96	1.82	1.83	1.80	1.85	1.86
-13		0.27	0.92	1.82	1.83	1.79	1.81	1.84
-17	S.W.	0.30	0.98	1.90	1.91	1.86	1.92	1.93
-18		0.28	0.92	1.81	1.82	1.79	1.84	1.83
-19		0.26	0.88	1.71	1.73	1.67	1.72	1.74
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

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

7.17 Clogging

NRq¹⁰

7.17.1 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 95 l/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 95 l/min continuous flow.

7.17.2 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 given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.

Note10: Single shift use only.

7.18 Demountable parts

Pass¹¹

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note11: Auxiliary hook are fitted with the ear straps, in accordance with the requirement.

9 Marking

NRq

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 (see 9.2.4).

Examples FFP3 NR D, FFP2 R D"

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

10 Information to be supplied by the manufacturer

NRq

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on:

application/limitations; the meaning of any colour coding; checks prior to use; donning, fitting; use; maintenance (e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

- fit of particle filtering half mask (check prior to use);
- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
- air quality (contaminants, oxygen deficiency);
- use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift."

Estimates of the uncertainty of measurement

Clause	Test	Uncertainty
7.4	Packaging	Not applicable
7.5	Material	Not applicable
7.6	Cleaning and disinfecting	Not applicable
7.7	Practical performance	See Note 1
7.8	Finish of parts	Not applicable
7.9.1	Total inward leakage	±4.4%
7.9.2	Penetration of filter material: Sodium chloride	±2.7%
7.9.2	Penetration of filter material: Paraffin oil	±3.2%
7.10	Compatibility with skin	Not applicable
7.11	Flammability	See Note 1
7.12	Carbon dioxide content of the inhalation air	±8.0%
7.13	Head harness	Not applicable
7.14	Field of vision	See Note 1
7.15	Exhalation valve(s)	See Note 1
7.16	Breathing resistance	±5.7%
7.17	Clogging	/
7.18	Demountable parts	Not applicable

Note 1 The acceptance criterion for this test is a straightforward “Pass/Fail”, rather than a numerical value. Consequently, as there is no value to be reported, uncertainty has not been reported either.

Note 2 The uncertainty value is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which provides for a confidence level of approximately 95%. Values expressed as a percentage (%) are relative.

Note 3 It should be noted that the above values have not been taken into account when making assessment to the pass/fail criteria.

End of Test Report.