INSPEC

56 LESLIE HOUGH WAY • SALFORD • GREATER MANCHESTER • M6 6AJ • UNITED KINGDOM
Email: testing@inspec-international.com Website: www.inspec-international.com
Tel: +44 (0)16 1737 0699 Fax: +44 (0)16 1736 0101

Test Report

EN 149 : 2001 + A1 : 2009

Particle filtering half masks

Report no: 1.18.10.73

Client: INSPEC Certification Services
56 Leslie Hough Way
Salford
Greater Manchester
M6 6AJ
United Kingdom

Manufacturer: SPRO Medical Products (Xiamen) Co., Ltd

Client order: TA18/0059

Order(s) received: 14 August 2017 to 19 October 2018

Model(s): GL001A
GL001

Date(s) of tests: 17 August 2017 to 26 October 2018

Signed: H Webb.

Issued: 2 November 2018

Heather Webb, Laboratory Supervisor

This report contains data previously reported in INSPEC Test Report number 1.18.05.08 revision 1 and INSPEC Test Report 1.17.09.82.

Conditions

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Opinions, comments and interpretations expressed in this report are shown in italics.

Copies of INSPEC interpretations referenced in this report are available upon request.

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Summary of assessment*

Clause		Submission:	Assessment (see Key)				
			One		Two		Three
		Model:	GL001	GL001A	GL001	GL001A	GL001
7.4	Packaging			Ltd			
7.5	Material		Ltd	Ltd	Ltd	Ltd	
7.6	Cleaning and disinfecting						
7.7	Practical performance		**Fail**	**Fail**	Pass	Pass	
7.8	Finish of parts		Ltd	Ltd	Ltd	Ltd	
7.9.1	Total inward leakage		Pass		Pass		
7.9.2	Penetration of filter material: Sodium chloride		Pass				
7.9.2	Penetration of filter material: Paraffin oil		**Fail**				Ltd
7.10	Compatibility with skin		Ltd				
7.11	Flammability		Pass				
7.12	Carbon dioxide content of the inhalation air			Pass			
7.13	Head harness		**Fail**	**Fail**	Pass	Ltd	
7.14	Field of vision		Ltd	Ltd	Pass	Pass	
7.15	Exhalation valve(s)		**Fail**		Pass		
7.16	Breathing resistance		Pass	Ltd	Ltd		
7.17	Clogging						
7.18	Demountable parts		NAp				
9	Marking						
10	Information to be supplied by the manufacturer						

Key

	Shading shows the clauses requested. Any other 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	GL001	GL001A
Classification claimed	FFP2 NR	
Exhalation valve(s)	One	None

Submission details

Submission one

Product	**Quantity**	**Date received**	**INSPEC specimen no. (1E0411 +)**
GL001A filtering half mask	30	9 August 2017	111 to 160
GL001 filtering half mask	65		201 to 260

Submission two

Product	**Quantity**	**Date received**	**INSPEC specimen no. (1F0090 +)**
GL001 filtering half mask	30	12 February 2018	101 to 160
GL001A filtering half mask	15		217 to 260

Submission three

Product	**Quantity**	**Date received**	**INSPEC specimen no. (1F0545 +)**
GL001 filtering half mask	5	10 October 2018	23 to 25, 60

Procedures

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

Testing was performed in accordance with BS EN 149 : 2001 incorporating corrigendum No. 1 (July 2002) and amendment A1 (March 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 by INSPEC.

7.7 Practical performance tests were conducted in simulation of the practical use of the apparatus under the conditions prevailing in the gallery area of the laboratory. The exercises undertaken and the equipment used were as specified in the standard.

The client instructed that practical performance testing be carried out on one specimen of each model of submission one.

7.9.2 Filter penetration testing by the paraffin oil method was carried out using a modified Phoenix SG-20 aerosol generator and a Phoenix model JM-6000 photometer or a TEC Services' model PH-3 photometer. These give similar performance to the instruments specified.

For the 120 mg exposure test, the peak penetration during exposure is reported and in addition the penetration after three minutes for comparison purposes.

During the 120 mg exposure test, the sodium chloride penetration showed continued decline and the test was terminated as the product was marked NR.

At the client's request, only three specimens of model GL001 of submission three were tested. All three against the paraffin oil aerosol following simulated wearing treatment (S.W.) in accordance with 8.3.1.

7.16 At the client's request, only six specimens of model GL001 of submission two were tested. Three following temperature conditioning (T.C.) in accordance with 8.3.2, one as received following flow conditioning (A.R. + F.C.) and two following temperature conditioning and flow conditioning (T.C. + F.C.).

Exhalation resistance was tested at a continuous flow of 160 l/min.

Result details

Submission one (1E0411)

7.4 Packaging

Model GL001A

The masks were not packaged as offered for sale. Manufacturer to determine final packaging. **NAs**

The masks were packaged in clear plastic bags in cardboard cartons that gave some protection against mechanical damage or contamination before use. **Pass**

7.5 Material

Model GL001A

The materials used were able to withstand handling and wear during the limited laboratory testing carried out. **Ltd**

The effect on materials from “in-use” environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors. **NAs**

Specimens 120 to 122 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse. **Pass**

Specimens 117 to 119 and 151 to 153 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse. **Pass**

The effects of filter media release were not assessed. Manufacturer to certify. **NAs**

Model GL001

The materials used were able to withstand handling and wear during the limited laboratory testing carried out. **Ltd**

The effect on materials from “in-use” environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors. **NAs**

Specimens 220 to 225 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse. **Pass**

Specimens 206 to 210, 217 to 219, 226 to 231, 233, 239, 240, 246, 247 and 251 to 255 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse. **Pass**

The effects of filter media release were not assessed. Manufacturer to certify. **NAs**

7.7 Practical performance

Model GL001A

Specimen and subject details:

Specimen	Subject	
148	ED	**Fail**
149	-	**NAs**

Subject ED commented that the head harness was very uncomfortable on the top of their ears.

Model GL001

Specimen and subject details:

Specimen	Subject	
248	AH	**Fail**
249	-	**NAs**

Subject AH commented that the head harness was very uncomfortable on the top of their ears.

7.8 Finish of parts

Model GL001A

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

Model GL001

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

7.9.1 Total inward leakage (%)

Model GL001

Subject	Specimen	Cond.	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
KRB	**201**	**A.R.**	0.19	0.74	1.11	2.77	0.49	1.06
KDS	**202**	**A.R.**	0.27	1.13	0.89	4.16	1.25	1.54
PBU	**203**	**A.R.**	0.14	0.11	0.29	0.21	0.17	0.18
INH	**204**	**A.R.**	0.24	0.20	0.21	0.53	0.12	0.26
GW	**205**	**A.R.**	0.24	0.27	0.29	0.83	0.26	0.38
CKN	**206**	**T.C.**	1.16	1.23	1.39	0.87	1.77	1.28
MD	**207**	**T.C.**	0.14	0.12	0.11	1.96	0.60	0.58
ED	**208**	**T.C.**	0.06	0.11	0.11	0.23	0.07	0.12
AH	**209**	**T.C.**	0.39	0.43	0.62	0.76	0.38	0.52
VE	**210**	**T.C.**	0.77	0.86	0.68	0.54	0.46	0.66
Maximum permitted			**11**					**8**

All 50 individual exercise results were not greater than 25%. **Pass**

All 10 individual wearer arithmetic means were not greater than 22%. **Pass**

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
KRB	108	130	108	49
KDS	102	128	98	49
PBU	116	141	90	52
INH	125	153	95	58
GW	117	133	120	53
CKN	112	145	114	54
MD	113	144	117	53
ED	114	138	100	47
AH	119	113	115	50
VE	116	132	115	45

7.9.2 Penetration of filter material

Model GL001

Sodium chloride: **Pass**

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
211	**A.R.**	0.27	
212		0.19	
213		0.19	
220	**S.W.**	1.36	
221		1.05	
222		0.92	
226	**M.S. + T.C.**	0.43	0.43
227		0.35	0.35
228		0.33	0.33
Maximum permitted		**6.0**	

Paraffin oil: **Fail**

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
214	**A.R.**	1.13	
215		1.47	
216		1.58	
223	**S.W.**	**6.09**	
224		2.93	
225		4.40	
229	**M.S. + T.C.**	1.92	2.59
230		1.80	2.26
231		1.80	2.37
Maximum permitted		**6.0**	

7.10 Compatibility with skin

Model GL001

No problems were encountered during limited practical performance testing. **Ltd**

No problems were encountered during total inward leakage testing. **Pass**

The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify. **NAs**

7.11 Flammability

Model GL001

Specimens 244 and 245 (A.R.) and 246 and 247 (T.C.) were tested. None of the specimens ignited. **Pass**

7.12 Carbon dioxide content of the inhalation air

Model GL001A **Pass**

Specimen	CO_2 (%)
135	0.53
136	0.58
137	0.56
Maximum permitted	**1.0**

7.13 Head harness

Model GL001A

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance. **Ltd**

Total inward leakage testing was not requested. **NAs**

The head harness was self-adjusting and while there were no adverse comments regarding security following limited practical performance, there were adverse comments regarding comfort of the harness, according to 8.4.1 a). See clause 7.7 for details. **Fail**

Inward leakage testing was not carried out; assessment of the performance of the harness could not be made. **NAs**

Model GL001

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance and total inward leakage testing. **Ltd**

The head harness was self-adjusting and while there were no adverse comments regarding security following limited practical performance, there were adverse comments regarding comfort of the harness, according to 8.4.1 a). See clause 7.7 for details. **Fail**

The product satisfied the total inward leakage requirements. See 7.9.1 for results. **Pass**

7.14 Field of vision

Model GL001A

There were no adverse comments following limited practical performance tests. **Ltd**

Model GL001

There were no adverse comments following limited practical performance tests. **Ltd**

7.15 Exhalation valve

Model GL001

The problems noted below were observed during function in all orientations. **Fail**

The exhalation valve on specimen 219 did not open on exhalation.

The valve was protected against dirt and mechanical damage by a cover. **Pass**

The product satisfied leakage requirements. See 7.9 for results. **Pass**

There were no observed problems when assessing operation after high exhalation flow. See 7.16 for results. **Pass**

The valve housing withstood 10 N applied for 10 s. Specimens 232 (A.R.), 233 (T.C.) and 234 (M.S.) were tested. **Pass**

7.16 Breathing resistance

Model GL001A **Ltd**

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
111	**A.R.**	Not requested		1.99
112				1.90
113				2.04
117	**T.C.**	Not requested		1.86
118				1.79
119				1.92
120	**S.W.**	Not requested		2.28
121				2.13
122				2.37
Maximum permitted				**3.0**

Model GL001 **Pass**

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
211	**A.R.**	0.43	1.45	1.09
212		0.38	1.37	1.17
213		0.44	1.62	1.16
217	**T.C.**	0.41	1.39	1.06
218		0.38	1.30	1.02
219		0.40	1.37	2.28
220	**S.W.**	0.46	1.72	1.27
221		0.45	1.51	1.13
222		0.44	1.52	1.18
238	**A.R. + F.C.**	0.42	1.43	1.18
239	**T.C. + F.C.**	0.38	1.33	1.08
240		0.34	1.22	1.12
Maximum permitted		**0.7**	**2.4**	**3.0**

7.18 Demountable parts

Model GL001

No demountable parts were used. **NAp**

Submission two (1F0090)

7.5 Material

Model: GL001

The materials used were able to withstand handling and wear during the limited laboratory testing carried out. **Ltd**

The effect on materials from “in-use” environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors. **NAs**

Specimens 120 to 122 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse. **Pass**

Specimens 106 to 110, 117 to 119, 133, 139, 140, 156 and 157 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse. **Pass**

The effects of filter media release were not assessed. Manufacturer to certify. **NAs**

Model: GL001A

The materials used were able to withstand handling and wear during the limited laboratory testing carried out. **Ltd**

The effect on materials from “in-use” environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors. **NAs**

Specimens 220 to 222 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse. **Pass**

Specimens 217 to 219 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse. **Pass**

The effects of filter media release were not assessed. Manufacturer to certify. **NAs**

7.7 Practical performance

Model: GL001

Specimen and subject details:

Specimen	Subject	
148	BH	**Pass**
149	VE	**Pass**

No adverse comments were made following testing.

Model: GL001A

Specimen and subject details:

Specimen	Subject	
248	ED	**Pass**
249	AH	**Pass**

No adverse comments were made following testing.

7.8 Finish of parts

Model: GL001

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

Model: GL001A

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

7.9.1 Total inward leakage (%)

Model: GL001

Subject	Specimen	Cond.	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
KDS	**101**	**A.R.**	1.16	1.31	1.00	1.31	1.01	1.16
GW	**102**	**A.R.**	0.41	0.47	0.49	1.09	0.45	0.58
ED	**103**	**A.R.**	1.55	2.23	2.17	0.89	1.20	1.61
CKN	**104**	**A.R.**	0.71	0.52	1.36	0.41	1.08	0.82
AH	**105**	**A.R.**	0.67	0.85	0.73	0.81	0.79	0.77
VE	**106**	**T.C.**	0.70	0.71	1.04	0.74	0.58	0.75
PBU	**107**	**T.C.**	0.60	0.46	0.60	0.95	0.76	0.67
BH	**108**	**T.C.**	0.61	0.62	0.65	1.09	0.48	0.69
INH	**109**	**T.C.**	0.51	0.51	0.51	0.83	0.50	0.57
EM	**110**	**T.C.**	1.65	1.89	1.79	1.25	0.75	1.46
Maximum permitted			**11**					**8**

All 50 individual exercise results were not greater than 25%. **Pass**

All 10 individual wearer arithmetic means were not greater than 22%. **Pass**

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
KDS	102	128	98	49
GW	117	133	120	53
ED	114	138	100	47
CKN	112	145	114	54
AH	119	113	115	50
VE	116	132	115	45
PBU	116	141	90	52
BH	120	139	108	54
INH	125	153	95	58
EM	122	142	127	51

7.13 Head harness

Model: GL001

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during practical performance and total inward leakage testing. **Pass**

The head harness was self-adjusting and there were no adverse comments regarding security following practical performance and total inward leakage testing. **Pass**

The product satisfied the total inward leakage requirements. See 7.9.1 for results. **Pass**

Model: GL001A

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during practical performance testing. Inward leakage testing was not carried out. **Ltd**

The head harness was self-adjusting and there were no adverse comments regarding security following practical performance leakage testing. Inward leakage testing was not carried out. **Ltd**

Inward leakage testing was not carried out; assessment of the performance of the harness could not be made. **NAs**

7.14 Field of vision

Model: GL001

There were no adverse comments following practical performance tests. **Pass**

Model: GL001A

There were no adverse comments following practical performance tests. **Pass**

7.15 Exhalation valve

Model: GL001

There were no observed problems during limited testing of function in all orientations. See 7.16 for results. **Ltd**

The valve was protected against dirt and mechanical damage by a cover. **Pass**

The product satisfied leakage requirements. See 7.9 for results. **Pass**

The valve housing withstood 10 N applied for 10 s. Specimens 132 (A.R.), 133 (T.C.) and 134 (M.S.) were tested. **Pass**

7.16 Breathing resistance

Model: GL001 **Ltd**

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)	
		At 30 l/min	At 95 l/min	At 160 l/min	
111	**A.R.**	Not requested	Not requested	Not requested	**NAs**
112					**NAs**
113					**NAs**
117	**T.C.**	0.43	1.50	1.09	**Pass**
118		0.42	1.50	1.06	**Pass**
119		0.42	1.56	1.02	**Pass**
120	**S.W.**	Not requested	Not requested	Not requested	**NAs**
121					**NAs**
122					**NAs**
138	**A.R. + F.C.**	0.46	1.62	1.09	**Pass**
139	**T.C. + F.C.**	0.39	1.38	1.02	**Pass**
140		0.38	1.30	1.00	**Pass**
Maximum permitted		**0.7**	**2.4**	**3.0**	

Submission three (1F0545)

7.9.2 Penetration of filter material

Model GL001

Paraffin oil: **Ltd**

Specimen	Condition	Penetration (%)		
		After 3 minutes	Max. during exposure	
-	A.R.	Not requested		NAs
-				NAs
-				NAs
23	S.W.	1.58		Pass
24		2.26		Pass
25		1.47		Pass
-	M.S. + T.C.	Not requested		NAs
-				NAs
-				NAs
Maximum permitted		6.0		

Estimates of the uncertainty of measurement

Clause	Test	Uncertainty
7.4	Packaging	Not applicable
7.5	Material	See Note 1
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	± 4.8%
7.9.2	Penetration of filter material - Sodium chloride	± 4.8%
7.9.2	Penetration of filter material - Paraffin oil	± 6.3%
7.10	Compatibility with skin	Not applicable
7.11	Flammability	See Note 1
7.12	CO_2 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	± 4.2%
7.17.2	Breathing resistance after clogging	± 7.7%
7.17.3	Filter penetration after clogging - Sodium chloride	± 4.8%
7.17.3	Filter penetration after clogging - Paraffin oil	± 6.3%
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.

ANNEX

This Annex comprises one section.

1. Photographs of the products tested. (5 pages)

END OF REPORT

SPRO Medical Products (Xiamen) Co., Ltd
model GL001A filtering half mask

INSPEC Testing Services' specimen number 1E0411 160 **5 September 2017**

SPRO Medical Products (Xiamen) Co., Ltd
model GL001 filtering half mask

INSPEC Testing Services' specimen number 1E0411 260 **5 September 2017**

SPRO Medical Products (Xiamen) Co., Ltd
Model GL001 filtering half masks

INSPEC Testing Services' specimen number 1F0090 160 **22nd February 2018**

SPRO Medical Products (Xiamen) Co., Ltd
Model GL001A filtering half masks

INSPEC Testing Services' specimen number 1F0090 260 **22nd February 2018**

SPRO Medical Products
model GL001 FFP2 NR filtering half mask

INSPEC Testing Services' specimen number 1F0545 60 **22 October 2018**