

Test Report SL52045313232001TX-1
OPHARM SP.Z O.O.
POKRZYWNICA 62,99-120 PIATEK.

Date: December 17, 2020 Page 1 of 10

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52045313232001TX DATE: 2020-12-15 ISSUED BY SGS (SHANGHAI) UPDATED TEST INFORMATION.

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

Sample Description : (A) Particle Filtering Half Mask
Sample Color : (A) WHITE
Style No. : OPP2
Test Performed : Selected test(s) as requested by applicant
Sample Receiving Date : Nov 24, 2020 & Nov 30, 2020
Testing Period : Nov 30, 2020 - Dec 15, 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)

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.



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



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.	4.68	3.54	4.03	3.74	4.14	4.03
Luo	2	A.R.	5.29	4.84	3.79	5.48	5.45	4.97
Lu	3	A.R.	4.20	4.01	3.13	5.19	5.04	4.31
Wang	4	A.R.	4.08	2.52	2.69	3.47	2.36	3.02
Bao	5	A.R.	5.69	4.33	4.44	5.04	6.52	5.20
Ding	6	T.C.	3.14	3.67	3.56	4.37	3.37	3.62
Li	7	T.C.	4.27	6.35	6.23	5.46	5.45	5.55
Chen	8	T.C.	3.01	4.90	3.64	4.11	2.52	3.64
Song	9	T.C.	5.54	4.08	4.67	4.73	4.70	4.74
Ye	10	T.C.	5.94	5.50	5.35	5.87	6.11	5.75

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
Ding	134	150	110	52

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.



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, Meet FFP3
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	0.320
		2	0.329
		3	0.315
	Simulated wearing treatment	4	0.321
		5	0.334
		6	0.326
		7	0.431
		8	0.459
		9	0.462
Paraffin oil test	As received	10	0.118
		11	0.126
		12	0.103
	Simulated wearing treatment	13	0.152
		14	0.143
		15	0.122
		16	0.392
		17	0.404
		18	0.443

Flow conditioning : Single filter: 95.0 L/min



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.

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	0.5826
	2	0.5833
	3	0.5821
		Mean value:0.58

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.



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	



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.

Clause 7.16 Breathing Resistance
(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement				Results	Comment
The breathing resistance 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)

As received	Flow rate(l/min)	1					2					3				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.3	0.3	0.4	0.4	0.3	0.4	0.4	0.4	0.3	0.4	0.3	0.4	0.4	0.4
	95	1.4	1.3	1.4	1.4	1.3	1.4	1.4	1.3	1.4	1.3	1.4	1.4	1.4	1.3	1.3
Exhalation	160	2.4	2.4	2.3	2.4	2.3	2.4	2.4	2.4	2.3	2.4	2.4	2.3	2.4	2.4	2.4
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	0.4	0.3	0.3	0.4	0.4	0.3	0.4	0.4	0.3	0.3	0.4	0.3	0.4	0.4
	95	1.3	1.4	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.4	1.3	1.3	1.3	1.4	1.4
Exhalation	160	2.3	2.4	2.4	2.4	2.3	2.3	2.3	2.4	2.3	2.4	2.4	2.3	2.3	2.3	2.4
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	0.3	0.3	0.4	0.4	0.3	0.4	0.4	0.3	0.3	0.3	0.4	0.4	0.3	0.4	0.3
	95	1.3	1.3	1.3	1.3	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.4	1.4	1.3	1.3
Exhalation	160	2.4	2.3	2.4	2.3	2.4	2.4	2.4	2.4	2.3	2.3	2.3	2.4	2.3	2.4	2.3

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



Clause 7.17 Clogging

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

Test Requirement	Results	Comment																			
<p>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.</p> <p>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</p>	Optional for single shift device only	N.A.																			
<p>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.</p> <table border="1"> <thead> <tr> <th rowspan="3">Classification</th> <th colspan="2">Maximum penetration of test aerosol</th> </tr> <tr> <th>Sodium chloride test 95 l/min</th> <th>Paraffin oil test 95 l/min</th> </tr> <tr> <th>%</th> <th>%</th> </tr> </thead> <tbody> <tr> <td></td> <td>max.</td> <td>max.</td> </tr> <tr> <td>FFP1</td> <td>20</td> <td>20</td> </tr> <tr> <td>FFP2</td> <td>6</td> <td>6</td> </tr> <tr> <td>FFP3</td> <td>1</td> <td>1</td> </tr> </tbody> </table>	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	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	Comply	Pass

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%

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.



Sample Photo



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.

3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com





End of Report

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com.

3rd Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666 f (86-21) 64958763
t (86-21) 61402666 f (86-21) 64958763

www.sgsgroup.com.cn
e sgs.china@sgs.com

