

Certificate F201965526

Guangzhou Biofil Air Purification Materials Co., Ltd.

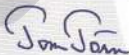
Room 201, 2nd floor, workshop B,
No 1, Doutang Road, YongHe Development Zone, Guangzhou, 511356,
P.R.China

It is certified that the manufacturer's technical file and the TPC product detailed on
page 2 have been assessed and found to be in accordance with:

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 15 May 2020 until 15 May 2025
1. Certified since 15 May 2020

Authorized by



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FINAS
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S003 (EN ISO/IEC 17065)

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Certificate F201955826, continued

Guangzhou Biofil Air Purification Materials Co., Ltd.

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

BIOFIL (logo) MY302, fold flat, single use Particle filtering half mask

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001 + A1:2005 (Respiratory protective devices – Filtering half masks to protect against particles) for a performance classification FFP2 NR

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference: BIOFIL-01 Revision 1 dated 2020-05-13

SGS Reference Number UKCRS 241072

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EU DECLARATION OF CONFORMITY

Manufacturer: Guangzhou Biofil Air Purification Materials Co., Ltd
Address: Room 201, 2nd floor, workshop B, No.1 Doutang Road, YongHe
Development Zone Guangzhou China

declares that the new PPE described hereafter

MY3D2 FFP2 NR Particle Filtering Half Mask

is in conformity with the Regulation (EU) 2016/425 and with harmonized
standard
EN 149:2001 + A1:2009

SGS Fimko Oy
Takomtie 8,
FI-00380 Helsinki,
Finland
Notified Body No.0598

performed the EU type-examination (Module B) Class III PPE category and
issued the EU type-examination certificate number: FI20/965826

The PPE is subject to the conformity assessment procedure conformity to type
based on quality assurance of the production process (Module D) under
surveillance of the notified body.

SGS Fimko Oy
Takomtie 8,
FI-00380 Helsinki,
Finland
Notified Body No.0598

Signed for on behalf of Company

Name:  Ye Jian Jie
Position: General Manager
Date: May 15th, 2020
Signature: 

SGS



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TESTING
CNAS L0599

Test Report

SL52025244872201TX

Date: April 29,2020

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GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO., LTD
ROOM 201, 2ND FLOOR, WORKSHOP B, NO.1 DOUTANG ROAD, YONGHE DEVELOPMENT ZONE,
GUANGZHOU, CHINA 511356

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

Sample Description : (A)Particle filtering half mask

Style No. : MY3D2

Composition : (A)non-woven fabrics

Sample Color : (A)White

Manufacturer : GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO., LTD

Country of Destination : European countries

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

Sample Receiving Date : Apr 15, 2020

Testing Period : Apr 15, 2020 - Apr 29, 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)



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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	Pass

Appendix 1: Summarization of Test Data**Inward Leakage Test Data**

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	8.13	8.23	8.28	8.18	8.31	8.2
Gong	2	A.R.	7.33	7.84	7.64	7.39	7.71	7.6
Yu	3	A.R.	5.90	6.47	6.32	5.90	6.32	6.2
Hu	4	A.R.	6.32	6.60	6.71	6.61	6.45	6.5
Xu	5	A.R.	7.89	8.07	8.00	8.04	8.10	8.0
Deng	6	T.C.	6.32	6.41	6.79	6.48	6.53	6.5
Liu	7	T.C.	5.62	5.88	5.87	5.93	5.80	5.8
Zhi	8	T.C.	6.11	6.60	6.53	6.49	6.22	6.4
Fang	9	T.C.	5.11	5.39	5.13	5.24	5.53	5.3
Chen	10	T.C.	7.77	7.77	7.88	8.09	8.17	7.9
All 50 individual exercise results were not greater than 11 %							Pass	
9 out of 10 individual wearer arithmetic means were not greater than 8 %								

Facial Dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63

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Test Report	SL52025244872201TX			Date: April 29,2020	Page 4 of 9
Fang	115	129	120	50	
Chen	116	150	132	56	
Lv	110	121	110	53	

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.				
Classification	Maximum penetration of test aerosol		Detail refer to Appendix 2	Pass
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min		
% 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 (%)	Assessment
Sodium chloride test	As received	11	0.682	Pass
		12	0.591	
		13	0.674	
	Simulated wearing treatment	14	0.726	
		15	0.731	
		16	0.745	
	Mechanical strength + Temperature conditioned	17	0.821	
		18	0.865	
		19	0.799	
Paraffin oil test	As received	20	1.24	
		21	1.31	
		22	1.35	
	Simulated wearing treatment	23	1.26	
		24	1.22	
		25	1.38	
	Mechanical strength + Temperature conditioned	26	1.49	
		27	1.47	
		28	1.45	
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 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	Assessment
As received	29	Burn for 2 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 1 s	

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	Assessment
As received	33	0.42%	Mean value 0.4% Pass
	34	0.42%	
	35	0.41%	

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	

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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	

Clause 7.16 Breathing Resistance#

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

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 5	Pass			
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		



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Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

As received	Flow rate		36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30 l/min		0.6	0.7	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.6	0.7	0.7	0.7	
	95 l/min		2.1	2.3	2.2	2.2	2.1	2.2	2.3	2.1	2.1	2.1	2.2	2.3	2.2	2.3	2.2
	160 l/min		2.6	2.8	2.7	2.8	2.7	2.7	2.7	2.8	2.7	2.7	2.8	2.7	2.6	2.6	2.6
Exhalation	30 l/min		0.7	0.7	0.7	0.6	0.6	0.7	0.7	0.6	0.7	0.6	0.7	0.6	0.7	0.7	0.6
	95 l/min		2.3	2.2	2.2	2.1	2.2	2.1	2.2	2.2	2.1	2.3	2.1	2.2	2.1	2.2	2.2
	160 l/min		2.8	2.7	2.6	2.8	2.8	2.7	2.7	2.7	2.7	2.7	2.7	2.8	2.7	2.6	2.7
Simulated wearing treatment	Flow rate		39					40					41				
	Inhalation	30 l/min	0.7	0.7	0.7	0.6	0.6	0.7	0.7	0.6	0.7	0.6	0.7	0.6	0.7	0.7	0.6
		95 l/min	2.3	2.2	2.2	2.1	2.2	2.1	2.2	2.2	2.1	2.3	2.1	2.2	2.1	2.2	2.2
Exhalation	160 l/min	2.8	2.7	2.6	2.8	2.8	2.7	2.7	2.7	2.7	2.7	2.7	2.8	2.7	2.6	2.7	
Temperature conditioned	Flow rate		42					43					44				
	Inhalation	30 l/min	0.7	0.7	0.7	0.7	0.7	0.6	0.7	0.6	0.7	0.6	0.7	0.7	0.6	0.7	0.7
		95 l/min	2.1	2.2	2.3	2.2	2.3	2.1	2.2	2.3	2.1	2.3	2.3	2.3	2.2	2.2	2.1
Exhalation	160 l/min	2.7	2.8	2.7	2.8	2.8	2.6	2.8	2.8	2.7	2.8	2.7	2.6	2.8	2.7	2.8	
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

Clause 7.17 Clogging#

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

Test Requirement	Results	Comment
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.	Optional for single shift device only	N.A.
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		



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Test Requirement			Results	Comment
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.				
Classification	Maximum penetration of test aerosol		Optional for single shift device only	N.A.
	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	No demountable parts	N.A.

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