



COVID-19 PPE & Medical Equipment

Certified. Reliable. Trusted.

Respirator Mask - FFP2



SHIELD WORKS

QUALITY PROTECTION EQUIPMENT

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Shield Works PPE

With 15 years of China manufacturing experience and a team of over 50 project managers and engineers, we have the infrastructure and knowledge to ensure that all medical products are supplied by approved manufacturers to required national standards. This eliminates the risk of bulk shipments being impounded by customs at port of entry.

The SW PPE Logistics Department is here to ensure your supply gets to where it needs to be with zero unnecessary delays. Our Planning & Ops coordinators are highly experienced and knowledgeable in customs regulations in China and all major overseas markets including the USA and the EU, especially in those related to PPE such as face masks.

The close relationships we have with customs agents and brokers built over 15 years of supply chain management in China means we always stay on top of the ever-changing customs rules. Nothing catches us by surprise.

We can charter entire cargo planes, converted passenger planes and organize regular air freight and sea freight.

Take the hassle, stress and risk out of this vital part of your supply chain by engaging with SW today.



Nick Cunningham QVCS

President & Founder

Major in HM Royal Marines (ret'd)



Mark Jacobs

CEO

1st Class Mechanical Engineer



Mark Clayton FMATT

CFO

Vice-Chairman of British Chamber of Commerce Guangdong;
2019 Peace Laureate



SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

CE FDA



- Light & Breathable
- Fit & Comfortable
- 5 Layers Protection
- Safety and Hygiene

Respirator Mask - FFP2

SKU: SW-FFP2

Packaging details

20 pcs per box / 1,000 pcs per carton

Carton Size: 50 x 30 x 50 cm

G.W.: 6.8 KG

CBM: 0.075

V.W.: 12.5 KG

Suitable for the protection of pathogens, pollen and dust

Executive standard

EN 149:2001+A1:2009



One Size
Fits All



Single
Use



Easy to put on
No strings to tie



5 Filtering
multi-layers



Light and
Breathable



Comfort
Ear Fit





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1 result found for **Owner Operator Name :**
Guangzhou Biofil [New Search](#)

Establishment Name	Registration Number	Current Registration Yr
GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO., LTD CHINA	No number listed	2020
<ul style="list-style-type: none"> Non-Surgical Isolation Gown - Coverall Isolation Gowns; Isolation Gowns; 		Manufacturer
<ul style="list-style-type: none"> Accessory, Surgical Apparel - Coverall Protective Clothing; Coverall Surgical Apparel; Disposable Face Masks; Disposable Surgical Mask 		Manufacturer
<ul style="list-style-type: none"> Respirator, Surgical - Disposable Protective Mask, KN95, Particle Filtering Half Mask, FFP2 NR 		Manufacturer
<ul style="list-style-type: none"> Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per lie Guidance - Disposable Face Mask; Disposable Protective Mask, KN95; Face Mask; KN95/FFP2 NR Disposable Protective Mask; Particulate Filtering Half Mask, FFP2 NR 		Manufacturer

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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

Certificate FI20/965826

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 PPE 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

Authorised by

SGS FIMKO OY, Notified Body 0598

Takomotie 8, FI-00380, Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com



Page 1 of 2



SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

Certificate FI20/965826, continued

Guangzhou Biofil Air Purification Materials Co., Ltd.

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

Issue 1

PPE Product

BIOFIL (logo) MY3D2, 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 + A1:2009 (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 UK/CRS 241072.

This certificate remains the property of SGS Fimko Oy Ltd to whom it must be returned to on request.





SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

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
Takomotie 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
Takomotie 8,
FI-00380 Helsinki,
Finland
Notified Body No.0598

This Declaration of conformity is valid in connection with the release document for the
respective batch of produced devices.


The above mentioned declaration of conformity is exclusively under the responsibility of

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

Signed for on behalf of Company

Name: York Zhang
Position: Quality Manager

Date: May 24, 2020

Signature: 



Respirator Mask - FFP2

EN149报告



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025244872201TX** **Date: April 29,2020** **Page 1 of 9**

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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EN149报告



Test Report

SL52025244872201TX

Date: April 29,2020

Page 2 of 9

Test Result

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





Respirator Mask - FFP2

EN149报告



Test Report

SL52025244872201TX

Date: April 29,2020

Page 3 of 9

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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Respirator Mask - FFP2

EN149报告



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.			Detail refer to Appendix 2	Pass
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 (%)	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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Respirator Mask - FFP2

EN149报告



Test Report

SL52025244872201TX

Date: April 29,2020

Page 5 of 9

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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Respirator Mask - FFP2

EN149报告



Test Report SL52025244872201TX Date: April 29,2020 Page 6 of 9

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																							
<table border="1"> <thead> <tr> <th rowspan="2">Classification</th> <th colspan="3">Maximum permitted resistance (mbar)</th> </tr> <tr> <th colspan="2">Inhalation</th> <th>Exhalation</th> </tr> <tr> <td></td> <th>30 l/min</th> <th>95 l/min</th> <th>160 l/min</th> </tr> </thead> <tbody> <tr> <td>FFP1</td> <td>0.6</td> <td>2.1</td> <td>3.0</td> </tr> <tr> <td>FFP2</td> <td>0.7</td> <td>2.4</td> <td>3.0</td> </tr> <tr> <td>FFP3</td> <td>1.0</td> <td>3.0</td> <td>3.0</td> </tr> </tbody> </table>			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
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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Respirator Mask - FFP2

EN149报告



Test Report

SL52025244872201TX

Date: April 29,2020

Page 7 of 9

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

	Flow rate	36					37					38					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
As received	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
	Exhalation	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
Simulated wearing treatment	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	2.8	2.7	2.6	2.7	2.7
Temperature conditioned	Inhalation	30 l/min	0.7	0.7	0.7	0.7	0.7	0.6	0.7	0.6	0.7	0.7	0.7	0.6	0.7	0.7	0.7
		95 l/min	2.1	2.2	2.3	2.2	2.3	2.1	2.2	2.1	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
<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.





Respirator Mask - FFP2

EN149报告



Test Report **SL52025244872201TX** Date: April 29,2020 Page 8 of 9

Test Requirement			Results	Comment																			
<p><u>Clause 7.17.3 Penetration of filter material</u> 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> <tr> <th></th> <th>max.</th> <th>max.</th> </tr> </thead> <tbody> <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	No demountable parts	N.A.

This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1499.



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Respirator Mask - FFP2

EN149报告



Test Report

SL52025244872201TX

Date: April 29,2020

Page 9 of 9

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

合格证 (Certificate of Compliance)

产品名称 (Product): 颗粒过滤半面罩 (Particle Filtering Half Mask, FFP2 NR)

型号 (Model): MY3D2

主要成分 (Components): 51%无纺布、21%纳米纤维过滤膜、28%热风棉
(51% Non-woven fabric, 21% Nano fabric, 28% Hot air cotton)

执行标准 (Standard): EN 149:2001+A1:2009

质检员 (Inspector): **QC PASSED**

产品批号 (Lot Number): 见包装喷码 (See the coding on the package)

生产日期 (Production Date): 见包装喷码 (See the coding on the package)

有效期 (Shelf life): 3 years

本产品经检验符合规定的质量标准, 准予出厂

本产品不得用于医疗用途 (Not for medical application)

生产厂商: 广州拜费尔空气净化材料有限公司

Manufacturer: Guangzhou Biofil Air Purification Materials Co., Ltd.

生产地址: 广州市经济技术开发区永和经济区斗塘路1号自编编号厂房B车间二楼201室

ADD: Room 201, 2ND floor, workshop B, No.1 DouTang Road,
YongHe Development Zone, Guangzhou, China




Made in China



SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2



BIOFIL™

Particle Filtering Half Mask

Please read this User Information Sheet carefully before using this product. This product complies with the requirements of EU Regulation (EU) 2016/425 for Personal Protective Equipment and meets the requirements of European standard EN149:2001+A1:2009.

Check before use
The mask must be selected properly for intended application. An individual risk assessment must be evaluated. Check the mask that it is undamaged with no visible defects. Check that the expiry date has not been reached (see the packaging). Check the protection class (FFP1 NR/ FFP2 NR/ FFP3 NR) is appropriate for the product used and its concentration. Do not use the mask if a defect is present or the expiry date has been exceeded.

This product is designed to protect against the risks:
These devices are designed to protect against both solid and liquid aerosols.

Risk	Standard Clause	Assessment method
Penetration of particle	EN 149:2001+A1:2009, clause 7.9.1 and 7.9.2	Total inward leakage test, Penetration of filter material


Usage / Limitations
Do not use out of the scope of use defined in the warnings. Failure to properly use this product may result in serious health damage or death.


FFP1 NR: Filter Efficiency 80%; Allocated Protection Factor (FPA) is 4; Examples of applications are Handling of stone / rubble / cellulose.

FFP2 NR: Filter Efficiency 94%; Allocated Protection Factor (FPA) is 10; Examples of applications are Sanding of soft wood, composite materials, rust, putty, plaster, plastics / cutting, deburring, grinding, drilling of metal.

FFP3 NR: Filter Efficiency 99%; Allocated Protection Factor (FPA) is 20; Examples of applications are Sanding of hard wood (beech, oak) / treatment of wood using copper, chrome or arsenic based products / impact stripping of paint / sanding of cement.

CE
0508
EN 149:2001+A1:2009

 End of shelf life

 Recommended conditions of storage

This product is intended to be worn by general public or healthcare personnel, and not intended for a medical purpose.

10 Pieces



Respirator Mask - FFP2



Particle Filtering Half Mask

Model: MY3D2

Easy to Use / Donning and fitting

Open the folded mask and hold it in your hand with the sharp corner on the outside, and let the head harness hang over your hand. Hold the mask over your chin and cover your nose. Fasten the mask on your head by pulling on the head harness. Place the tips of two fingers on the nose clip, starting from the middle position, press the nose clip with your finger inward, and move and press to the sides respectively to shape the nose clip and fit your face.

The mask shall be disposed according to local waste regulations and shall not be discarded randomly.

Warnings

1. Failure to follow all instructions and limitations on the use of this product, or failure to achieve proper fit, may result in damage to your health or death.
2. A properly selected mask is essential to protect your health. Before using this mask consult a suitably qualified safety professional to determine the suitability of the product for your intended use.
3. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this mask when the oxygen concentration is less than 19.5%.
4. Do not use when concentrations of contaminants are immediately dangerous to health or life. Do not use this product in an explosive atmosphere.
5. Leave the work area immediately if: a) breathing becomes difficult or b) dizziness or other distress occurs.
6. Facial hair, beards and certain facial characteristics may reduce the effectiveness of this mask.
7. Never alter or modify this mask in any way (except as indicated in the instructions).
8. "NR" means this particle filtering half mask shall not be used for more than one shift. No maintenance is necessary. Discard mask after use or if damaged in any way.
9. The length of time this mask can be used depends on contaminants present but should not exceed one shift. The mask should be replaced sooner if breathing becomes difficult.
10. Keep mask in the display box away from direct sunlight or contaminants until use. Ambient storage conditions as temperature between -30°C to +70°C, and relative humidity <80%.
11. Unless this is fitted according to the "Easy to use" instructions the mask will not provide the expected level of protection.
12. This mask is suitable for use in protection against the non-toxic solid and liquid aerosols.
13. Failure to achieve proper fit may result in serious health damage or death.
14. See information supplied by the manufacturer.
15. The mask must be stored and transported in their original package and protected by the storage temperature and humidity as suggested by the manufacturer.

	CE mark
FFP2 NR	Protection category
EN 149:2001+A1:2009	European standard number

 Guangzhou Biofil Air Purification Materials Co., Ltd.
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Fax: +86-20-32811688-802 E-mail: info@jetbiofil.com
EU declaration of conformity can be accessed at <https://www.jetbiofil.com/page.html?id=34>

EU type-examination for Regulation
(EU) 2018/425 by
Notified Body Number: 0598
SGS Fimko Oy,
Tukimotie 8, FI-00380 Helsinki,

Made in China



SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2



营业执照

(副本)

编号 S0112015014809 (1-1)

统一社会信用代码 91440101304301689J

名称	广州拜费尔空气净化材料有限公司
类型	有限责任公司(外商投资企业法人独资)
住所	广州市经济技术开发区永和经济区斗塘路1号自编号 厂房B车间二楼201室
法定代表人	袁建华
注册资本	伍佰万元整
成立日期	2014年07月11日
营业期限	2014年07月11日至 2024年07月07日
经营范围	橡胶和塑料制品业(具体经营项目请登录广州市商事主体信息公示平台查询。依法须经批准的项目,经相关部门批准后方可开展经营活动。)



登记机关



2018年04月26日



Respirator Mask - FFP2



**CHINA CHAMBER OF COMMERCE FOR
IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS**

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CCCMHPIE Released the Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

Saturday, 25 April 2020 | Source: CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS | Author:

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

Updated: 6 May, 2020

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No.	Company	Uniform Social Credit Code	Status of Certification / Authorization in Other Countries
一、	医用口罩 Medical Face Masks		
52	广州拜费尔空气净化材料有限公司 Guangzhou Biofil Air Purification Materials Co., Ltd.	91440101304301689J	CE



SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

中华人民共和国医疗器械注册证

注册证编号：粤械注准 20202140604

注册人名称	广州拜费尔空气净化材料有限公司
注册人住所	广州市经济技术开发区永和经济区斗塘路1号自编号厂房B车间二楼201室
生产地址	广州市经济技术开发区永和经济区斗塘路1号自编号厂房B车间二楼201室
产品名称	医用外科口罩（疫情应急产品）
型号、规格	平面型，17.5cm×9.5cm
结构及组成	由口罩体、鼻夹和口罩带组成。口罩体由非织造布（内外层）、聚丙烯熔喷布（中间层）构成。非无菌提供，一次性使用。
适用范围	供临床医务人员在有创操作过程中佩戴，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、体液、颗粒物等的直接透过提供物理屏障。
附件	产品技术要求。
其他内容	无
备注	本产品按照《广东省防控新型冠状病毒感染的肺炎疫情防控药品医疗器械行政许可应急审批程序》批准，注册证有效期1年，到期后应当及时提出注册延续注册应当在医疗器械注册证有效期届满6个月前提出。

审批部门：广东省药品监督管理局

批准日期：2020年05月14日
有效期至：2021年05月13日





SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Respirator Mask - FFP2

证明

兹证明广州拜费尔空气净化材料有限公司（以下简称“子公司”）系我司全资子公司，
我司控股比例为 100%子公司基本情况：

子公司于 2014 年 07 月 11 日经广州市黄埔区市场监督管理局登记在广州市经济技术
开发区永和经济区斗塘路 1 号自编号厂房 B 车间二楼 201 室设立，统一社会信用代码：
91440101304301689J，法定代表人：袁建华。

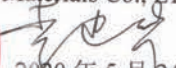
This is to certify that Guangzhou Biofil Air Purification Materials Co., LTD. (Hereinafter
referred to as the "subsidiary") is a wholly-owned subsidiary of our company, and our holding
ratio is 100%. Basic information of the subsidiary: The subsidiary was registered by the
market supervision administration of Guangzhou Huangpu District on July 11, 2014 in room
201, 2nd floor, workshop B, workshop no. 1, Doutang road, Yonghe Development Zone,
Guangzhou, with unified social credit code: 91440101304301689J and legal representative:
Yuan Jianhua.

特此证明！

Hereby certify!


广州洁特生物过滤股份有限公司
Guangzhou Jet Bio-Filtration Co., Ltd

广州拜费尔空气净化材料有限公司
Guangzhou Biofil Air Purification Materials Co., LTD.


2020 年 5 月 24 日

May.24.2020



SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

To: Whom it may concern

Letter of Authorization

Whereas, Guangzhou Biofil Air Purification Materials Co., Ltd. located at **Room 201, 2nd floor, workshop B, No 1. Doutang Road, YongHe Development Zone, Guangzhou, 511356, China;** an established & reputable manufacturer of: **Particle filtering half mask.**

We do hereby authorize our Regional General Agent:

CHINA 2 WEST SERVICES LTD. and its subsidiary SHIELD WORKS

to be sales representative in **the territories of USA, UK and EU** to offer and supply our products.

We assure to supply, good quality products guaranteed as Manufacturer's standard. Thank you for considering our products as your preferred choice.

Please do not hesitate to contact us if further clarification is required.
Your Sincerely,

VALIDITY: 05.23.2020 – 05.23.2021

Signature of authorized representative of the manufacturer:

Manufacturer Stamp:


**Guangzhou Biofil Air Purification
Materials Co., Ltd.**





EC DECLARATION OF CONFORMITY

Manufacturer

Name: Guangzhou Biofil Air Purification Materials Co., Ltd.

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

Authorized Representative

Name: China 2 West Services Limited

Address: Flat /RM 16E, Neich Tower, 128 Gloucester Rd, Wanchai, HongKong

Declares that the MDD described hereafter

Product name and model:

Particle Filtering Half Masks, FFP2 NR MY3D2

The product is certified to meet the Essential requirements and relevant provisions of EU Regulation: EU 2016/425

Standard(s)/Directive(s):
EN 149:2001+A1:2009

as shown in the test reports:

SL52025244872201TX

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Company: tChina 2 West Services Limited
Address Flat /RM 16E, Neich Tower, 128 Gloucester Rd, Wanchai, HongKong

Zhuhai China, 2020-05-23

Place, date

Expiry date: 2021-05-23



Mark Clayton, Group CFO
Legally binding signature

EC Declaration of Conformity

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Get in touch

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