



Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200227-018-FPC-B

Certificate holder:	SHANDONG SHENGQUAN NEW MATERIALS CO., LTD Diaozhen Industrial Development Zone, Zhangqiu, Jinan, China
The scope of the certification for:	The manufacture of respiratory protective devices See annex for articles covered by this certificate
Validity from:	2020-04-10
To:	2021-04-09

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation. The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index. The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid. This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15,
D15 AKK1, Ireland

Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie

If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

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(Fm220-016, Rev.1)



Schedule of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200227-018-FPC-B

Product reference and description		Reference standard
Particle filtering half mask	Model: SNN70370B	EN 149:2001 + A1:2009
Particle filtering half mask	Model: SNN70369B	EN 149:2001 + A1:2009
Particle filtering half mask	Model: SNN200647	EN 149:2001 + A1:2009

Certificate Revision.	Revision details	Revision date
B	Initial issue	2020-04-10

This schedule has no validity without the accompanying certificate.

This schedule and the accompanying certificate remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

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Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200227-018-01-9C

Certificate holder:	Shandong Shengquan New Materials Co., Ltd. Diaozhen Industrial Development Zone, Zhangqiu, Jinan, China
Product:	Particle filtering half masks Detailed product description listed in the Annex
Model(s):	See Annex
Standard(s):	EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-04-10
Revision date:	2020-06-18
Expiry date:	2025-04-09

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.

Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.

CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.

If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.

This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



Approved by:



Owen Bian, Office Manager

CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15,
D15 AKK1, Ireland

Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie

If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

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Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200227-018-01-9C

Applicable standards and specification:

EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
SNN70370B	Folding particle filtering half mask with adjustment ear loops without valves, internal metal nose clip Class: FFP2 NR Test report No.:2020(D) - 0005
SNN70369B	Folding particle filtering half mask with adjustment ear loops without valves, internal metal nose clip Class: FFP2 NR Test report No.:2020(D) - 0004

Certificate Revision	Revision date	Revision details
B	2020-04-10	Initial issue
C	2020-06-18	Editorial change to description to include ear loops



CCQS Certification Services Limited

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SHENGQUAN

SHANDONG SHENGQUAN NEW MATERIALS CO LTD.
ADD: Diaozhen Industrial Development Zone, Zhangqiu, Shandong, China
TEL: 0086-531-83501239/83511609 FAX: 0086-531-83511356
Web: www.shengquan.com E-Mail: sqwmb@shengquan.com

EU Declaration of conformity
for personal protective equipment
according to Regulation (EU) 2016/425



Name of the Manufacturer: **Shandong Shengquan New Materials Co., Ltd.**
Address: **Diaozhen Industrial Development Zone, Zhangqiu, Jinan, China**

Product name: **Particle filtering half mask**
Models/ REFs : **SNN200647, SNN70370B, SNN70369B**

We, as a manufacturer of the above products, hereby declare that the above Personal Protective Equipment (PPE) products are in conformity with the provisions of Regulation (EU) 2016/425, including fulfilment of the applicable essential health and safety requirements set out in Annex II, and with the National Standard transposing the harmonised European Standard Number

EN 149:2001+A1:2009

and are identical to the PPE which are the subject of EU type-examination (Module B of Regulation (EU) 2016/425) referenced on the following certificates:

CE-PC-200324-094-01-9C (issue date 10.04.2020)

CE-PC-200227-018-01-9C (issue date 10.04.2020)

issued by

CCQS Certification Services Limited, Block 1 Blanchardstown Corporate Park,
Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Ireland

and are subject to the procedures set out in Module D of Regulation (EU) 2016/425 under the surveillance of CCQS (Notified Body number 2834).

Signed by: Chuanwei Xu



President

Date: 18th June 2020



**National Quality Supervision and
Testing Center for Personal
Protective Equipment (Beijing)**

No.55 Taoranting Street, Xicheng District,
Beijing, China.
Phone: +86 10 63519250
Fax: +86 10 63519250

The Testing Center is accredited for compliance with ISO/IEC 17025.

The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.
CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Particulate respirator-half facepiece

**EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles —
Requirements, testing, marking**

Product: Biomass Graphene Particulate Respirator

Report No: 2020 (D) - 0004

Client: CCQS UK LTD

Contact: Hu Xiaoming

Model (s): SNN70369B

Date(s) of tests: 2020.03.11-2020.03.24

DESCRIPTION OF SAMPLES

General Information	Classification	Main Components
Manufacturer	FFP2 NR	Grey folding mask
Manufacturer Address	Shandong Shengquan New Materials Co., Ltd	
	Industry Development Zones, Diaozhen Town, Zhangqiu, Shandong	

Signed:

Issued: 2020.3.25

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

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国家劳动防护用品质量监督检验中心(北京)

Test Results

7.3 Visual inspection

Pass

The visual inspection shall include the marking and information supplied by the manufacturer.

7.4 Package

Pass¹

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.

Note1: In accordance with the requirement.

7.5 Material

Pass²

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.

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

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note2: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting

N/A³

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.

Note3: Single shift use only.

7.7 Practical performance

Pass⁴

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

Note4: No imperfections.

7.8 Finish of parts

Pass⁵

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

Note5: No sharp edges or burrs.

7.9.1 Total inward leakage

Pass⁶

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

Note6: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material

Pass⁷

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%

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FFP3 $\leq 1\%$ $\leq 1\%$ **Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.****7.10 Compatibility with skin****Pass⁸**

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.

Note8: No irritation or any other adverse effect to health.**7.11 Flammability****Pass⁹**

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.

Note9: Test results are shown in Annex A Table 7.11.**7.12 Carbon dioxide content of the inhalation air****Pass¹⁰**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Note10: Test results are shown in Annex A Table 7.12.**7.13 Head harness****Pass¹¹**

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note11: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.**7.14 Field of vision****Pass¹²**

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

Note12: Pass the practical performance tests.**7.15 Exhalation valve****N/A¹³**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note13: No exhalation valve.**7.16 Breathing resistance****Pass¹⁴**

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

Note14: FFP2 respirator. Test results are shown in Annex A Table 7.16.

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7.17 CloggingN/A¹⁵**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

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

7.17.3 Penetration of filter material

Sodium chloride test 95 l/min

FFP1 ≤ 20%

FFP2 ≤ 6%

FFP3 ≤ 1%

Note15: Single shift use only.

Paraffin oil test 95 l/min

≤ 20%

≤ 6%

≤ 1%

7.18 Demountable parts

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

Note16: No demountable parts.N/A¹⁶**9 Marking**

Not tested

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.**9.1.2** Type-identifying marking.**9.1.3** Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable.

Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.**9.1.5** At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.**9.1.6** The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.**9.1.7** The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.**9.1.8** The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.**9.2 Particle filtering half mask**

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.**9.2.2** Type-identifying marking.

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9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

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

End of Test Results

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Annex A: Summarization of Test Data**Table 7.9.1-A Inward leakage test data**

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	5.74	5.85	5.83	5.83	5.74	5.8
Gong	2	A.R.	5.67	5.72	5.89	5.82	5.71	5.8
Yu	3	A.R.	4.43	4.56	4.52	4.66	4.55	4.5
Zhi	4	A.R.	4.61	4.78	4.86	4.85	4.72	4.8
Fang	5	A.R.	4.81	4.93	5.05	5.17	5.06	5.0
Hu	6	T.C.	5.34	5.49	5.51	5.59	5.43	5.5
Xu	7	T.C.	5.33	5.57	5.54	5.48	5.49	5.5
Deng	8	T.C.	5.48	5.65	5.57	5.63	5.47	5.6
Zhang	9	T.C.	5.42	5.52	5.69	5.54	5.54	5.5
Liu	10	T.C.	5.56	5.61	5.78	5.76	5.61	5.7
50 out of the 50 individual exercise results \leq 11 % 10 of the 10 individual arithmetic means \leq 8 %					Pass			

Table 7.9.1-B 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
Fang	115	129	120	50

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Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	1.51	Pass
		12	1.65	
		13	1.52	
	Simulated wearing treatment	14	1.56	
		15	1.63	
		16	1.68	
	Mechanical strength+ Temperature conditioned	17	1.59	
		18	1.57	
		19	1.61	
Paraffin oil test	As received	20	4.84	Pass
		21	4.91	
		22	5.15	
	Simulated wearing treatment	23	4.92	
		24	5.36	
		25	5.29	
	Mechanical strength+ Temperature conditioned	26	5.27	
		27	5.34	
		28	5.31	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2 s	Pass
	30	Burn for 2 s	
Temperature conditioned	31	Burn for 2 s	
	32	Burn for 3 s	

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国家劳动保护用品质量监督检验中心(北京)

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60144577 0001

Report No.: 15096008 008

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE
301-307 LOCKHART ROAD, WAN CHAI
HONG KONG
P.R. China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: DD 60113159 0001

Expiry Date: 2021-08-21

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-08-25

Date: 2020-08-25

Notified Body

Herbert Zhong



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60144577 0001
Report No.: 15096008 008

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE
301-307 LOCKHART ROAD, WAN CHAI
HONG KONG
P.R. China

Products:

- Warmers
- Cold Packs
- Hot Packs

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Disposable Surgical Masks
- Disposable Surgical Gowns
- Disposable Surgical Caps
- Surgical Drapes

Date: 2020-08-25

Notified Body

Herbert Zhong



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60144577 0001
Report No.: 15096008 008

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE
301-307 LOCKHART ROAD, WAN CHAI
HONG KONG
P.R. China

Sites included:

Shanghai Intco Electrode Manufacturing Co., Ltd.
No. 1358, Hubin Road, Fengxian District,
Shanghai 201417, China

Aspects of manufacture concerned with securing and
maintaining sterile conditions of Disposable Surgical Masks,
Disposable Surgical Gowns, Disposable Surgical Caps,
Surgical Drapes

Jiangsu Intco Medical Products Co., Ltd.
No. 77 Yandunshan Road, Dagang, Zhenjiang,
Jiangsu Province 212132, China

Warmers, Cold Packs, Hot Packs

Date: 2020-08-25

Notified Body

Herbert Zhong



ZERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE



EC DECLARATION OF CONFORMITY

Manufacturer

Name: **INTCO Medical (HK) Co., Ltd.**
Address: **Flat/RM 19c, Lockhart Centre
301-307 Lockhart road, Wan Chai,
Hong Kong**

Authorized Representative

Name: **Lotus NL B.V.**
Address: **Koningin Julianaplein 10,
1e Verd, 2595AA, The Hague,
Netherlands.**

Declares that the MDD described hereafter
Product name and model:

Disposable Medical Masks UMDNS code: 12458

Meet the provisions of the Council Directive 93/42/EEC which apply to the Masks.
Verification to: Standard EN 14683-2019

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



CONFORMITY ASSESSMENT ROUTE: ANNEX IX Rule 1

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: INTCO Medical (HK) Co., Ltd.
Address: Flat/RM 19c, Lockhart Centre 301-307 Lockhart road, Wan Chai, Hong Kong

Shanghai 2019-05-20

Place, date

For and on behalf of
INTCO MEDICAL (HK) CO., LIMITED
英科醫療用品(香港)有限公司

.....
Legally binding signature and function signature(s)