

FFP2 Schutzmaske (Konformitätserklärung, Zertifikate & Test Report)



EU-Konformitätserklärung

Hersteller:

Handelsmarke:

Produktname:

Modell: BS-9502C

Einstufung: PSA (EU) 2016/425, Kategorie III

Konformitätsbewertung:

Einhaltung nach EU Verordnung (EU) 2016/425

Hiermit erklären wir, dass die oben genannten Produkte der Umsetzung in nationales Recht, den Bestimmungen der folgenden EU-Verordnung und Normen entsprechen. Alle unterstützenden Dokumentationen werden in den Räumlichkeiten des Herstellers aufbewahrt.

Für die Erklärung ist ausschließlich der Hersteller verantwortlich und trifft auf die allgemein gültige Verordnung zu:

Verordnung: (EU) 2016/425

Angewandte Normen/Standards:

EN 149:2001 + A1:2009

Der Test Report und die Zertifikate wurden von der benannten Stelle 2834 CCQS Certification Services Limited ausgestellt.

Unterschrift:

Name:

Stellung:

Ort/Datum:



Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.:

Certificate holder:

Product:

Model(s):

Standard(s):

Issue date:

Revision date:

Expiry date:

Particle filtering half masks
Detailed product description listed in the Annex

See Annex

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

2020-04-04

2020-04-04

2025-04-03



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This certificate remains the property of CCQS and may be withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.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



CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15.
D15 AOK1, Ireland
Tel: +353 1 908 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
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Module B EU Type-Examination Certificate
Annex

For the requirements of PPE Regulation 2016/425
 Certificate No.: [REDACTED]

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
BS-9501L	Folding particle filtering facepiece without valve and twin elastic headbands Class: FFP2 NR Test Report NO: [REDACTED]
BS-9501FL	Folding particle filtering facepiece with exhalation and twin elastic headbands Class: FFP2 NR Test Report NO: [REDACTED]
BS-9502C	Folding particle filtering facepiece without valve and twin elastic headbands Class: FFP2 NR Test Report NO: [REDACTED]
BS-9502FC	Folding particle filtering facepiece with exhalation and twin elastic headbands Class: FFP2 NR Test Report NO: [REDACTED]

Certificate Revision	Revision date	Revision details
A	2020-04-04	Initial issue



CCQS Certification Services Limited
 Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15,
 D15 AXK1, Ireland
 Tel: +00 353 1 588 6620 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
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Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: [REDACTED]

Certificate holder: [REDACTED]

The scope of the certification for: The manufacture of respiratory protective device

Validity from: 2020-04-04
 To: 2021-04-03



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 may be 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 AXK1, Ireland
 Tel: +00 353 1 588 6620 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
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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.: [REDACTED]

Product reference and description		Reference standard
Particle filtering half mask	Model: BS-9501L	EN 149:2001 + A1:2009
Particle filtering half mask	Model: BS-9501FL	EN 149:2001 + A1:2009
Particle filtering half mask	Model: BS-9502C	EN 149:2001 + A1:2009
Particle filtering half mask	Model: BS-9502FC	EN 149:2001 + A1:2009

Certificate Revision	Revision details	Revision date
A	Initial issue	2020-04-04

This schedule has no validity without the accompanying certificate. This schedule and the accompanying certificate remain the property of CCQS and may be withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



CCQS Certification Services Limited
 Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15,
 D15 ARK1, Ireland
 Tel: +00 353 1 588 8020 Website: www.ccqs.ie E-mail: info@ccqs.ie
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EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products



Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
Particle filtering half mask	BS-9501L	FFP2 NR	
Particle filtering half mask	BS-9501FL	FFP2 NR	
Particle filtering half mask	BS-9502C	FFP2 NR	
Particle filtering half mask	BS-9502FC	FFP2 NR	

The Manufacturer's name and address is as follows:

Name: [REDACTED]
 Address: [REDACTED]



This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Detailed description of the PPE to allow traceability/identification of the PPE.

BS-9501L	White folder half mask without valve	
BS-9501FL	White folder half mask with exhalation valve.	



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BS-9502C	White folder half mask without valve	
BS-9502FC	White folder half mask with exhalation valve	

The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:




No.	EU Type Examination (Module B) Certificate Number
1	

Product Category:

This product is Category II.

This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834).

This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834).

Signature:  Date:  Company stamp and/or legal signature: 




National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing)
(Testing Laboratory for Labour Protection Products of Beijing Municipal Institute for Labour Protection)
No.55 Taoranting Street, Xicheng District, Beijing, China.
Phone: +86 10 63519250 +86 10 63520770 +86 10 83530311
Fax: +86 10 63519250 +86 10 63520770

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: Particle filtering half mask
Report No: 
Client: CCQS Certification Services Limited
Model (s): BS-9502 C
Date(s) of tests: 2020.03.18-2020.03.31

DESCRIPTION OF SAMPLES

General Information	Classification	Main Components
Manufacturer	FFP2 NR	White folding mask
Manufacturer Address		

Signed: 
陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Issued: 2020.3.31

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Conditions:

The test results presented in this report relate to the samples tested only.
 This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.
 The authenticity of this test report and its contents can be verified by contacting the laboratory.
Note. This test report is the replacement and cancellation for test report No. 2020 (D) – 0021.

7.3 Visual inspection	Not tested¹									
The visual inspection shall include the marking and information supplied by the manufacturer. <i>Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.</i>										
7.4 Package	Pass²									
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. <i>Note2: In accordance with the requirement.</i>										
7.5 Material	Pass³									
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. <i>Note3: 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.</i>										
7.6 Cleaning and disinfecting	N/A⁴									
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. <i>Note4: Single shift use only.</i>										
7.7 Practical performance	Pass⁵									
The particle filtering half mask shall undergo practical performance tests under realistic conditions. <i>Note5: No imperfections.</i>										
7.8 Finish of parts	Pass⁶									
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. <i>Note6: No sharp edges or burrs.</i>										
7.9.1 Total inward leakage	Pass⁷									
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 <i>Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.</i>										
7.9.2 Penetration of filter material	Pass⁸									
The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.										
	<table border="0"> <tr> <td></td> <td>Sodium chloride test 95 l/min</td> <td>Paraffin oil test 95 l/min</td> </tr> <tr> <td>FFP1</td> <td>≤20%</td> <td>≤20%</td> </tr> <tr> <td>FFP2</td> <td>≤6%</td> <td>≤6%</td> </tr> </table>		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min	FFP1	≤20%	≤20%	FFP2	≤6%	≤6%
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min								
FFP1	≤20%	≤20%								
FFP2	≤6%	≤6%								
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FFP3 ≤1% ≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin Pass⁹
 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.
 Note9: No irritation or any other adverse effect to health.

7.11 Flammability Pass¹⁰
 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.
 Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air Pass¹¹
 The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)
 Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness Pass¹²
 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.
 Note12: 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 Pass¹³
 The field of vision is acceptable if determined so in practical performance tests.
 Note13: Pass the practical performance tests.

7.15 Exhalation valve N/A¹⁴
 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.
 Note14: No exhalation valve.

7.16 Breathing resistance Pass¹⁵

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

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

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7.17 Clogging N/A¹⁶

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	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note16: Single shift use only.

7.18 Demountable parts Pass¹⁷
 All demountable parts (if fitted) shall be readily connected and secured, where possible by hand
 Note17: In accordance with the requirement.

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



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.	7.31	7.41	7.54	7.43	7.47	7.4
Gong	2	A.R.	7.44	7.59	7.65	7.53	7.48	7.5
Yu	3	A.R.	7.38	7.45	7.53	7.41	7.43	7.4
Zhi	4	A.R.	6.55	6.65	6.73	6.62	6.56	6.2
Fang	5	A.R.	6.73	6.87	6.99	6.83	6.83	6.9
Hu	6	T.C.	7.38	7.44	7.57	7.49	7.43	7.5
Xu	7	T.C.	7.65	7.69	7.74	7.65	7.60	7.7
Deng	8	T.C.	7.46	7.55	7.65	7.59	7.42	7.5
Zhang	9	T.C.	7.77	7.89	7.93	7.88	7.72	7.8
Liu	10	T.C.	7.69	7.78	7.83	7.76	7.67	7.7
50 out of the 50 individual exercise results \leq 11%						Pass		
10 of the 10 individual arithmetic means \leq 8%								

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

