

EU Type Examination Certificate

Holds Certificate Number: CE 728275

In respect of:

Model WD-95 Face mask.

To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425.

PPE for use by healthcare professionals as per Commission recommendation 2020/403.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-05-19

Latest Issue: 2020-05-19

Drs. Dave Hagenaaars, Managing Director

Effective Date: 2020-05-19

Expiry Date: 2021-05-19

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EU Type Examination Certificate

No. CE 728275

Product Specification

Product Name: Partulate Respirator.

Product Type: Filtering half masks for use by Healthcare professionals.

Model: WD-95

Technical Specification: Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

Product Description: The respirator is non-reusable, secured to the face of the user by a pair of elasticated straps, and has no exhalation valve. The respirator is approved to GB 2626-2006 as KN95 product. The mask is a vertical fold flat design.

The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread.

The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.

Product Assessments: GB 2626-2006 Standard KN95

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A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 728275

Certificate Administration Details

Technical File Reference: TF-001 Revision 1.

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
May 2020	First issue.	2797:20:3202448

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 728277.

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Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

Holds Certificate Number: CE 728277

In respect of:

For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-05-19

Latest Issue: 2020-05-19



Drs. Dave Hagenars, Managing Director

Effective Date: 2020-05-19

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Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 728277

Product details

The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

Product type:	Particulate filtering half masks for use by Healthcare professionals.
Model and classifications:	WD-95 KN95
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 728277

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
May 2020	First issue.	2797:20:3202450

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

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Latest Issue: 2020-05-19

Effective Date: 2020-05-19

Expiry Date: 2021-05-19

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**Test Report
(2016/425 PPE)**

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Introduction.

This report has been prepared by Paul Waller and relates to the activity detailed below:

Job/Registration Details	
Job number:	3182763/1 of 2 Issue 2
Job type:	Testing Samples Submitted
Start Date:	28/04/2020
Test type:	Type
Sample ID:	10180319
Registration:	CE 728275
Scheme:	Negative pressure RPE
Protocol:	PP123
Scheme Manager:	Nathan Shipley

The report has been approved for issue by M Mayo – Testing Team Manager

Approved For Issue	
	Issue Date: 7 May 2020

Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:

BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers.

Product Scope.

COVID-19 masks for use by healthcare workers.

Report Summary.

The samples were received on 28 April 2020 and the testing was started on 28 April 2020.

This issue supersedes all previous issues. The amendment giving rise to this issue can be ascertained by contacting the authorizing signatory at the address shown.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 19	10180319	Model: WD-95 Disposable Protective Mask

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: WD-95 Disposable Protective Mask

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Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories

Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.

Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.

Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.

Fail: Non-compliance. Product does not meet the requirements of this clause.

Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.

N/T: Not Tested

N/A: Not Applicable

AR: As Received

TC: Temperature Conditioned

SW: Simulated Wear

FT: Flow Tested

MS: Mechanical strength

MMDF: Manufactures Minimum Design Flow

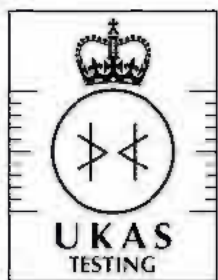
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
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Hertfordshire
HP2 4SQ



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Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.

Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Requirements.

Testing in accordance with BSI COVID-19 filtering face piece technical specification

Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
7.7 Practical performance 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. <i>2 test subjects, masks tested 'As received'</i>	Testing shall be done in accordance with 8.4.	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	Pass
7.9 Leakage 7.9.1 Total inward leakage <i>5 test subjects, masks tested 'As received'</i>	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage 7.9.2 Penetration of filter material <i>3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test</i>	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air <i>3 test samples, masks tested 'As received'</i>	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance <i>3 test samples, masks tested 'As received'</i>	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale) If achieves cl 7.9.2 FFP3 class 30l/min – 1.0mbar (inhale) 95l/min – 3.0mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

Test Results.

Testing in accordance with BSI COVID-19 filtering face piece technical specification

BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	<p>Practical performance</p> <p>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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.</p> <p>Test in accordance with clause 8.4 of the standard.</p> <p>Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers</p> <p>During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.</p>	Pass

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
RF1	1 AR	Good	Good	Perfect	None	Pass
GR1	2 AR	OK	Good	OK	Ear loop adjuster behind ear causes some minor discomfort	Pass

7.9 Leakage

7.9.1

Total inward leakage

The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.

Test in accordance with clause 8.5 of the standard.

Pass

Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers

5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)					Average	Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking		
AA1	3	AR	5.01	3.78	9.23	4.21	3.28	5.10	Pass
MM2	4	AR	3.29	3.26	3.21	2.56	1.87	2.84	Pass
GR1	5	AR	4.08	2.90	5.44	3.13	3.43	3.80	Pass
OR1	6	AR	3.92	4.01	7.12	4.87	4.45	4.87	Pass
SR1	7	AR	3.05	4.82	5.96	3.28	4.89	4.40	Pass

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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7.9.2 Penetration of filter material

Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers

3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl

Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
8	AR	95	< 6	0.0039
9	AR			0.0031
10	AR			0.0027

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	0.0721
12	AR			0.0797
13	AR			0.0732

7.12 Carbon dioxide content of inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).

Pass

Test in accordance with clause 8.7 of the standard.

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO ₂ (%)	
		Limit	Measured
14	AR	< 1.0	0.41
15	AR		0.47
16	AR		0.42

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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7.16

Breathing resistance

Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers

3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.

The breathing resistances shall meet the requirements of FFP2;
 30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)
 If achieves clause 7.9.2 FFP3 class (<1% penetration);
 30l/min – 1.0mbar (inhale), 95l/min – 3.0mbar (inhale), 160l/min – 3.0mbar (exhale)

Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 1.0	0.41
18	AR			0.48
19	AR			0.42
17	AR	95	< 3.0	1.29
18	AR			1.78
19	AR			1.32

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	2.09
18	AR			1.98
19	AR			2.21

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
RF1	105	122	120	55	548	Male
AA1	125	144	130	48	580	Male
MM2	119	150	114	52	592	Male
GR1	124	146	126	49	591	Male
SR1	117	133	131	52	586	Male
OR1	112	123	114	48	555	Female

Note: All candidates were clean shaven

Product photographs.



End of Report