Test Report 3257438.

[redacted]

Introduction.

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

Job/Registration Details		Client Details
Job number:	**3257438**	[redacted]
Job type:	Testing Samples Submitted	
Start Date:	05/08/2020	
Test type:	Type	
Sample ID:	10191542	
Registration:	**CE 732712**	
Scheme:	Negative pressure RPE	
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 19 October 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 27 July 2020 and the testing was started on 5 August 2020.

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

Test Samples.

Sample ID	ER Number	Description
1 to 19	10191542	Model: ZD3-FWJ, FFP3.

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: ZD3-FWJ, FFP3.

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. *2 test subjects, masks tested 'As received'*	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** *3 or 5 subjects with samples AR (see criteria)*	Testing shall be done in accordance with 8.5.	Test 3 subjects - If the 3 tests produce results between 1.5% and 2% mean or individual results over 5%, test 5 subjects If 5 tests undertaken; 23 of the 25 individual exercise results tests shall be not greater than 5 % (for FFP3) and, in addition, 4 of the 5 arithmetic means for the total inward leakage shall be not greater than 2 % (for FFP3)	Pass
7.9 Leakage **7.9.2 Penetration of filter material** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	1% for both PO and NaCl (FFP3)	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	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 *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of FFP3; 30l/min – 1.0mbar (inhale) 95l/min – 3.0mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

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.

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UKAS TESTING
0135

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 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	**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. Test in accordance with clause 8.4 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *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

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
JB1	1 AR	OK	OK	OK	None	Pass
JW1	2 AR	OK	OK	OK	None	Pass

Test Results.

CLAUSE	REQUIREMENTS	ASSESSMENT
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. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *Test 3 subjects - If the 3 tests produce results between 1.5% and 2% mean or individual results over 5%, test 5 subjects* *If 5 tests undertaken;* *23 of the 25 individual exercise results tests shall be not greater than 5% (for FFP3) and, in addition, 4 of the 5 arithmetic means for the total inward leakage shall be not greater than 2% (for FFP3)*	Pass (1) (2)

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)					
			A	B	C	D	E	
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average
KH1	3	AR	1.0296	1.0950	0.8709	0.8621	1.1971	1.0109
JA1	4	AR	0.2611	0.2521	0.2681	0.5506	0.2595	0.3183
JS3	5	AR	5.2187	3.5866	4.2100	0.8796	3.7794	3.5349
MM2	6	AR	0.1871	0.2666	0.2141	0.2032	0.2109	0.2164
LM2	7	AR	0.0705	0.0925	0.0568	0.0568	0.0491	0.0650

(1) Testing was performed using the ear strap clips provided with the samples.
(2) 24 of the 25 individual exercise results were not greater than 5%. 4 of the 5 arithmetic means were not greater than 2%.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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. 1.0% 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	< 1.0	0.0519
9	AR			0.0562
10	AR			0.0390

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	< 1.0	0.2145
12	AR			0.3770
13	AR			0.2635

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	0.45
15	AR		0.40
16	AR		0.40

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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 FFP3;* *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	0.54
18	AR			0.46
19	AR			0.51
17	AR	95	< 3.0	1.67
18	AR			1.47
19	AR			1.62

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	2.61
18	AR			2.30
19	AR			2.49

Appendix A. – Test Panel Data

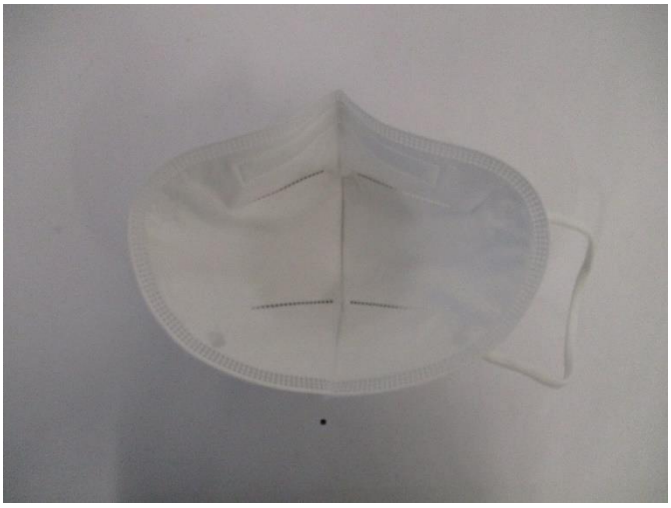
Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
KH1	112	142	115	60	585	Male
JA1	117	134	129	49	565	Male
JS3	126	134	124	49	600	Male
MM2	119	150	115	53	595	Male
LM2	110	148	125	44	589	Female
JB1	114	144	108	59	574	Male
JW1	116	126	122	48	570	Male

Note: All candidates were clean shaven

Product photographs.

Front view

Side view



Inside view

*** End of Report ***

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	[redacted]
Product name	Protective face mask (Single use unvalved)
Model/ Serial No.	ZD3-FWJ FFP3
Technical Reference:	BSI's PPE Technical Specification for Healthcare Professionals during the Covid-19 Pandemic
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	BSI Group - NB 2797 The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Notified body for EU type-examination (Module C2)	BSI Group - NB 2797 The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Certificate number	CE 732712

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

[redacted]

EU Type Examination Certificate

This is to certify that:

[redacted]

Holds Certificate Number: CE 732712

In respect of:

Model ZD3-FWJ FFP3 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):

Drs. Dave Hagenaars, Managing Director

First Issued:
Latest Issue:

Effective Date:
Expiry Date:

PRODUCTS RvA C 646

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Product Specification

Product Name:	Disposable Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**ZD3-FWJ**
Classification:	FFP3 NR Un-Valved.
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 Silicone ear straps. The respirator is FFP3 class, vertical fold flat type. 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:	BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

Certificate Administration Details

[redacted]

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
January 2021	First issue.	2797:21:3257520

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 732713.

Medical Device Management

CERTIFICATION EUROPE

Certificate of Registration

Certificate No.: [illegible]

This is to Certify that the Medical Devices Industry Management System of

[redacted]

Has been audited to the following Medical Devices Industry Management System standard:

ISO13485:2016

This approval is valid for the:

Production and sales of disposable medical device (including disposable surgical mask, medical surgical mask (sterile and non-sterile), medical protective mask, medical disposable protective clothing(sterile and non-sterile)

Date of issue: Mar. [illegible], 2020 — Date of expiry: Mar. [illegible], 202[illegible]

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit confirmation mark is in the designated position on the certificate.

IAF

Issued by:

12months | 24months

CERTIFICATION EUROPE [illegible] www.[illegible]