Test Report 3218331.

Unimama B.V.

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Introduction.

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

Job/Registration Details		Client Details
Job number:	**3218331**	Unimama B.V.
Job type:	Testing Samples Submitted	Sloterweg 315
Start Date:	15/05/2020	Badhoevedorp
Test type:	Type	1171 VC
Sample ID:	10190064	The Netherlands
Registration:	**CE 729819**	
Scheme:	Positive 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: 29 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 7 May 2020 and the testing was started on 15 May 2020.

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

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Test Samples.

Sample ID	ER Number	Description
1 to 19	10190064	Model: IRYS-01

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: IRYS-01

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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** *5 test subjects, masks tested 'As received'*	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** *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	6% for both PO and NaCl	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; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

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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.

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UKAS TESTING
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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	
JB2	1 AR	OK	OK	Good	Air leak towards eyes on exhale	Pass
JS3	2 AR	Quite tight	OK	OK	None	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 (%)						Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
CB1	3	AR	2.76	3.46	3.29	3.28	3.38	3.23	Pass
GR1	4	AR	3.62	4.58	2.98	3.67	2.42	3.45	Pass
BH2	5	AR	0.53	0.77	0.62	0.66	0.99	0.71	Pass
JA1	6	AR	2.79	2.76	2.31	2.33	2.87	2.61	Pass
JB1	7	AR	1.34	1.96	0.74	1.40	2.57	1.60	Pass

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. 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	0.434
9	AR			0.376
10	AR			0.641

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	2.768
12	AR			1.556
13	AR			1.854

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	0.40
15	AR		0.44
16	AR		0.42

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.	Pass
	The breathing resistances shall meet the requirements of FFP2; *30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	

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	< 0.7	0.47
18	AR			0.40
19	AR			0.40
17	AR	95	< 2.4	1.51
18	AR			1.31
19	AR			1.28

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	2.36
18	AR			2.10
19	AR			2.10

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Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
JB2	111	135	118	52	550	Male
JS3	126	134	124	49	600	Male
GR1	124	145	126	49	590	Male
CB1	117	147	130	57	566	Male
BH2	124	148	120	51	595	Male
JA1	117	134	129	49	565	Male
JB1	114	144	108	59	574	Male

Note: All candidates were clean shaven

Product photographs.

Front view

Side View

Inside View

End of Report

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