



3266139 - Test Report.

Test Report 3266139.

Ministerie van Volksgezondheid,
Welzijn en Sport



3266139 - Test Report.

Introduction.

This report has been prepared by O. Refoyo and relates to the activity detailed below:

Job/Registration Details	Client Details
Job number: 3266139 Job type: Testing Samples Submitted Start Date: 14/07/2020 Test type: Type Sample ID: 10191753	Ministerie van Volksgezondheid, Welzijn en Sport Parnassusplein 5 's-Gravenhage 2511 VX Netherlands

The report has been approved for issue by 5.1.2e

Approved For Issue	
5.1.2e	Issue Date: 17 September 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 6 July 2020 and the testing was started on 14 July 2020.

The samples submitted did not comply with the requirements of the test work conducted.



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Test Samples.

Sample ID	ER Number	Description
1 to 19	10191753	Model: Order 3057-23164 LOT 1458

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: Order 3057-23164 LOT 1458



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>3 or 5 subjects with samples AR (see criteria)</i>	Testing shall be done in accordance with 8.5.	Test 3 subjects - If the 3 tests produce results between 6% and 8% mean or individual results over 11%, test 5 subjects If 5 tests undertaken; 23 of the 25 individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, 4 of the 5 arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Fail
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	Fail
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)	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

M MDF: Manufactures Minimum Design Flow

M MDC: 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.

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

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ



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.



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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
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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.

Pass

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.

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
JW1	1 AR	OK	OK	OK	None	Pass
AH1	2 AR	OK	OK	OK	None	Pass



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Test Results.

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9	Leakage	
7.9.1	<p>Total inward leakage</p> <p>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.</p> <p>The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.</p> <p>Test in accordance with clause 8.5 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><i>Test 3 subjects - If the 3 tests produce results between 6% and 8% mean or individual results over 11%, test 5 subjects</i></p> <p><i>If 5 tests undertaken;</i></p> <p><i>23 of the 25 individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, 4 of the 5 arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)</i></p>	Fail

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E	Average	
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking		
LM2	3	AR	12.2642	22.7263	31.1155	13.0664	15.4658	19.1276	Fail
SI1	4	AR	22.2175	22.1583	21.6156	2.4502	18.9794	17.4842	Fail
AA1	5	AR	4.9103	6.1820	6.0874	5.5263	5.7118	5.6836	Pass
JS2	6	AR	1.3394	1.7966	1.6611	1.0538	1.2469	1.4196	Pass
CB1	7	AR	5.7584	5.2158	4.2081	3.2179	5.1917	4.1784	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 <i>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</i>	Fail																		
	Table C: Clause 8.11 - Sodium Chloride penetration test <table border="1"> <thead> <tr> <th rowspan="2">Sample number</th> <th rowspan="2">Pre-test condition</th> <th rowspan="2">Flow through filter (l/min)</th> <th colspan="2">Penetration (%)</th> </tr> <tr> <th>Limit</th> <th>Actual</th> </tr> </thead> <tbody> <tr> <td>8</td> <td>AR</td> <td rowspan="3">95</td> <td rowspan="3">< 6</td> <td>1.8793</td> </tr> <tr> <td>9</td> <td>AR</td> <td>1.4933</td> </tr> <tr> <td>10</td> <td>AR</td> <td>0.9201</td> </tr> </tbody> </table>	Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)		Limit	Actual	8	AR	95	< 6	1.8793	9	AR	1.4933	10	AR	0.9201	
Sample number	Pre-test condition				Flow through filter (l/min)	Penetration (%)														
		Limit	Actual																	
8	AR	95	< 6	1.8793																
9	AR			1.4933																
10	AR			0.9201																
	Table D: Clause 8.11 - Paraffin oil penetration test <table border="1"> <thead> <tr> <th rowspan="2">Sample number</th> <th rowspan="2">Pre-test condition</th> <th rowspan="2">Flow through filter (l/min)</th> <th colspan="2">Penetration (%)</th> </tr> <tr> <th>Limit</th> <th>Actual</th> </tr> </thead> <tbody> <tr> <td>11</td> <td>AR</td> <td rowspan="3">95</td> <td rowspan="3">< 6</td> <td>11.1845</td> </tr> <tr> <td>12</td> <td>AR</td> <td>11.8775</td> </tr> <tr> <td>13</td> <td>AR</td> <td>11.1660</td> </tr> </tbody> </table>	Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)		Limit	Actual	11	AR	95	< 6	11.1845	12	AR	11.8775	13	AR	11.1660	
Sample number	Pre-test condition				Flow through filter (l/min)	Penetration (%)														
		Limit	Actual																	
11	AR	95	< 6	11.1845																
12	AR			11.8775																
13	AR			11.1660																
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). Test in accordance with clause 8.7 of the standard.	Pass																		
	Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air <table border="1"> <thead> <tr> <th rowspan="2">Sample</th> <th rowspan="2">Pre-test condition</th> <th colspan="2">Dead space CO₂ (%)</th> </tr> <tr> <th>Limit</th> <th>Measured</th> </tr> </thead> <tbody> <tr> <td>14</td> <td>AR</td> <td rowspan="3">< 1.0</td> <td>0.45</td> </tr> <tr> <td>15</td> <td>AR</td> <td>0.45</td> </tr> <tr> <td>16</td> <td>AR</td> <td>0.45</td> </tr> </tbody> </table>	Sample	Pre-test condition	Dead space CO ₂ (%)		Limit	Measured	14	AR	< 1.0	0.45	15	AR	0.45	16	AR	0.45			
Sample	Pre-test condition			Dead space CO ₂ (%)																
		Limit	Measured																	
14	AR	< 1.0	0.45																	
15	AR		0.45																	
16	AR		0.45																	



3266139 - Test Report.

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 (inhalation), 95l/min – 2.4mbar (inhalation), 160l/min – 3.0mbar (exhalation)

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	< 0.7	0.39
18	AR			0.43
19	AR			0.40
17	AR	95	< 2.4	1.29
18	AR			1.39
19	AR			1.31

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	2.07
18	AR			2.30
19	AR			2.05

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
LM2	110	148	125	47	567	Male
SI1	121	135	142	48	575	Male
AA1	125	144	130	47	581	Male
JS2	126	142	125	57	575	Male
CB1	117	147	130	57	566	Male
JW1	116	126	122	48	570	Male
AH1	108	124	130	46	570	Male

Note: All candidates were clean shaven

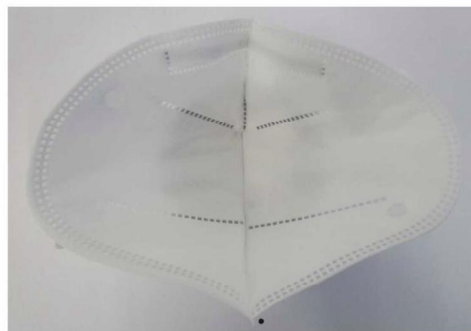
Product photographs.



Front view



Side view



Inside view

*** End of Report ***