

Test Report 3232800 Issue 3.

Motex Healthcare Corp.



Introduction.

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

Job/Registration Details		Client Details
Job number: Job type: Start Date: Test type: Sample ID: Registration: Scheme: Protocol: Scheme Mgr:	3232800 Issue 3 Testing Samples Submitted 15/06/2020 Type 10190509 CE 731044 Positive pressure RPE PP123 Nathan Shipley	Motex Healthcare Corp. No. 38-1, Xingong 5th Rd. Tianzhong Town Changhua County 520 Taiwan

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

Approved For Issue	
20/2	
	Issue Date: 18 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 15 June 2020 and the testing was started on 17 June 2020.

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

Issue 3 of this report supersedes all previous issues. The amendments on all pages giving rise to this issue can be ascertained by contacting the authorising signatory. This issue was to correct the Model number referenced in this report.



Test Samples.

Sample ID	ER Number	Description
1 to 19	10190509	Model: 99895A FFP2 3D Shape respirator

Description of Test Samples.

Sample Description

COVID-19 masks for use by healthcare workers:

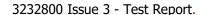
Model: 99895A FFP2 3D Shape respirator



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

chnical testing specification for COVII EN 149:2001+A1:2009	EN 149:2001+A1:2009		A
Performance requirement	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	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	1		





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 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.



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.	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:	

Table A: Practical performance

Task		Comments				
Test candidate	Sample	Head harness comfort	Security of fastenings	Field of vision	Any other comments	Assessment
JB1	1 AR	OK	OK	Good	None	Pass
JS2	2 AR	OK	OK	OK	None	Pass

a) head harness comfort; b) security of fastenings; c) field of vision; d) any other

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.

comments reported by the wearer on request.

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

able b. cla	usc 7.5.1	i Otal Ilivva	ra icakage						
				Inward Leakage (%)					
Test	Cample	Pre test	Α	В	С	D	Е		
candidate	Sample	condition	Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	Assessment
AH1	3	AR	2.928	3.122	2.986	2.990	2.938	2.993	Pass
JS3	4	AR	0.148	0.146	0.126	0.089	0.148	0.131	Pass
BH1	5	AR	0.075	0.070	0.213	0.115	0.118	0.118	Pass
JS2	6	AR	0.209	0.307	0.546	0.077	0.070	0.242	Pass
SI1	7	AR	0.306	4.386	0.087	0.181	0.049	1.002	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	Pre-test	Flow through filter (I/min)	Penetra	ation (%)
number	condition	Flow through filter (I/min)	Limit	Actual
8	AR			0.310
9	AR	95	< 6	0.285
10	AR			0.348

Table D: Clause 8.11 - Paraffin oil penetration test

Sample	Pre-test	Flow through filter (I/min)	Penetra	ation (%)
number	condition	Flow till ough filter (1/111111)	Limit	Actual
11	AR			1.088
12	AR	95	< 6	1.469
13	AR			2.246

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

Cample	Due test sandition	Dead spac	e CO ₂ (%)
Sample	Pre-test condition	Limit	Measured
14	AR		0.53
15	AR	< 1.0	0.55
16	AR		0.65



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

Table 11 Clause of D. Calaming Concession Limited Control of Calamine Calamine Control								
Sample	Pre-test condition	Continuous flow	Inhalation resistance (mbar)					
		(l/min)	Limit	Measured				
17	AR		< 0.7	0.37				
18	AR	30		0.42				
19	AR			0.41				
17	AR		< 2.4	1.25				
18	AR	95		1.40				
19	AR			1.38				

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 (I/min)	Exhalation resistance (mbar)		
			Limit	Measured	
17	AR		< 3.0	2.22	
18	AR	160		2.42	
19	AR			2.45	



Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	Sex
AH1	108	124	130	46	570	Male
JS3	126	134	124	49	600	Male
BH1	120	126	120	58	565	Male
JS2	126	142	125	57	575	Male
SI1	121	135	142	48	575	Male
JB1	114	144	108	59	574	Male

Note: All candidates were clean shaven

Product photographs.





Front view



Inside view ***End of Report***