REPORT NO: 2970



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REPORT

On the testing of

Transparent Face Masks to the Technical specification

https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe/transparent-face-mask-technical-specification

Using the methods in EN14683:2019+AC:2019
Documented in house methods:
M0121 BR, M0122 SP, M0124 MC, M0125 BFE

Report Prepared by:

Anthony Hanson



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Identification

Mask Description: Alpha Solway Haika MXC masks with clear panel

Mask size: 9.4 by 21.9 cm folded Manufacturer: Globus Group Ltd

4ward Sample No:2970 S1Customer reference:09000Date received:16/06/2021

Test Summary

	M1	M2	М3	M4	M5	Threshold	Result
Bacterial filtration efficiency (BFE), [%] 5.2.2	99.98	99.99	99.94	99.81	99.93	≥ 98	Pass
Breathability 5.2.3 (differential pressure) average of 5 areas/mask [Pa/cm2]	22.74	22.29	22.09	21.64	22.78	< 60	Pass
Splash resistance pressure 5.2.4 [kPa]	30 of 32 masks passed at 16kPa					≥ 29 @16kPa	Pass
Microbial cleanliness 5.2.5 (Bioburden) [cfu/g]	23.76	68.14	15.93	11.06	59.60	≤ 30	Fail

Test thresholds in line with a type IIR mask

Deviations from the test method

Whilst it is not possible to test impervious sections of the mask to enable full compliance with EN 14683 for a Type IIR for BFE and breathability, the Transparent Mask Technical Specification provides alternative methods. The alternative methods used in this report are as follows:

For BFE:

A combination of the filter area and transparent area were tested together, to assess the combined filtration efficiency, this is achieved by placing adjacent areas over the test apparatus orifice, with approximately half of each material covering the orifice, and the join/seam running through the centre.

For Breathability:

Only Permeable sections of the mask tested.

The Transparent Mask Technical Specification prohibits masks complying with that specification from being labelled as Type IIR masks."

Test Details

The Face Masks were tested as received from the customer.

Testing of the Transparent Face Masks was carried out to the following sections of EN 14683:2019+AC:2019

Bacterial Filtration Efficiency Section 5.2.2 (Modified test surface)

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Test area: 49 cm²
Exposed face: Inside
Test flow rate: 28.3L/min

Sample size: Full mask expanded (>10x10cm)

Mean plate counts

Positive controls: 8616.5 cfu Negative control 0 cfu

The positive controls were above the specification limit creating a harsher test and increasing the risk of false fails. The customer was informed of the harsher test conditions and was happy to proceed with the results as the samples had passed under the higher loading.

Sample pre-conditioning: >4h @ 21±5°C 85±5%RH

BFE for each test specimen shown in summary table.

Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk < 5%.

Breathability Section 5.2.3 (modified)

Only Permeable sections of the mask tested
Test area:
4.9±0.4 cm²
Test quantity:
5 masks

Test positions: 5 spanning out from the central clear window.

Test flow rate: 8L/min

Sample pre-conditioning: >4h @ 21±5°C 85±5%RH

		Mask1	Mask2	Mask3	Mask4	Mask5
Differential pressure [Pa/cm²]	1	23.51	22.36	21.02	19.50	22.94
	2	22.74	21.02	21.22	20.07	23.13
	3	22.36	22.74	21.41	24.27	23.32
	4	22.74	21.79	24.08	19.50	21.60
	5	22.36	23.51	22.74	24.85	22.94
	Average	22.74	22.29	22.09	21.64	22.78

Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk < 5%.

Splash Resistance Section 5.2.4

The test was carried out in accordance with ISO 22609:2004

A combination of areas targeted to assess transparent material, seam integrity and filter material.

Conditioned for >4h at 21±5 °C 85±5 % RH

Tested at 21±5 °C 85±10 % RH

No targeting plate was used

32 masks tested

30 masks Passed

Minimum of 29 Passes required

Pass - The Test passed the requirement AND had a conformance probability, pc>95 % for test conditions (Conditioning and test temperature and RH, synthetic blood surface tension and spray velocity)

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Microbial Cleanliness Section 5.2.5

Packaging description: Individually wrapped in Alpha Solway boxes

300 ml of extraction liquid (1 g/l Peptone, 5 g/l Sodium Chloride and 2 g/l Polysorbate Surfactant 20)

The bottle is laid down on an orbital shaker and shaken for 10 min at 250 rpm.

100 ml of the extraction liquid is filtered through a 0,45 μ m filter and laid down on a TSA plate. TSA plates incubated at 30±2°C

100 ml Aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with Chloramphenicol for Fungi Enumeration.

SDA Plates incubated at 20 to 25 °C

5 Masks tested

The total Bioburden is expressed by addition of the TSA and SDA counts divided by mask mass for cfu/g

	M1	M2	М3	M4	M5
Mass [g]	4.42	4.52	4.52	4.52	4.48
Total bioburden (whole mask)	105	308	72	50	267
Bioburden per gram [cfu/g]	23.76	68.14	15.93	11.06	59.60

Fail - One or more measured values were observed out of tolerance at the points tested. The specific false reject risk is < 5%.

Date of testing: 21/06-29/06/2021

These results relate only to the samples tested

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Work carried out and recorded by the following personnel:

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Work approved by the following personnel:

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Anthony Hanson

Quality Assurance Engineer

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