



REPORT NO: 3006-1



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REPORT

On the testing of

Medical Face Masks to EN14683:2019+ AC:2019
Documented in house methods:
M0124 MC

Report Prepared by:

Anthony Hanson



Identification

Mask Description: Alpha Solway Haika MXC masks with clear panel. Pale blue with earloops.
 Mask size: 9.4 by 21.9 cm folded
 Manufacturer: Globus Group Ltd
 4ward Sample No: 3006 S1
 Customer reference: 09657
 Date received: 26/07/2021

Test Summary

| | M1 | M2 | M3 | M4 | M5 | Threshold | Result |
|---|-------|-------|-------|------|-------|-----------|--------|
| Microbial cleanliness 5.2.5 (Bioburden) [cfu/g] | 29.84 | 25.80 | 25.14 | 9.65 | 14.74 | ≤ 30 | Pass |

Threshold for type IIR mask

Test Details

The Face Masks were tested as received from the customer

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

Microbial Cleanliness Section 5.2.5

Packaging description: masks in individual sealed packaging
 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 µm 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 | M3 | M4 | M5 |
|------------------------------|-------|-------|-------|------|-------|
| Mass [g] | 3.82 | 3.76 | 3.7 | 3.73 | 3.8 |
| Total bioburden (whole mask) | 114 | 97 | 93 | 36 | 56 |
| Bioburden per gram [cfu/g] | 29.84 | 25.80 | 25.14 | 9.65 | 14.74 |

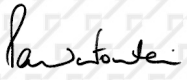
Conditional Pass – The measured values were observed in tolerance at the points tested. However, a portion of the expanded measurement uncertainty intervals about one or more measured values exceeded tolerance. When the measured result is close to the tolerance, the specific false accept risk is 49.1%.

Date of testing: 10/08/2021-17/08/2021

These results relate only to the samples tested




Work carried out and recorded by the following personnel:

 2021.08.18
15:53:46
+0100
Paula Fountain BSc MSc
Operations Manager

 Date:
2021.08.18
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Work approved by the following personnel:

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Anthony Hanson
Quality Assurance Engineer

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