

JOB NO: 3166
REPORT NO: 2488



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REPORT

On the testing of

Medical Face Masks to EN14683:2019+AC:2019
Documented in house methods:
M0121, M0122, M0124, M0125

Supplied by:

Sharon Services (UK) Ltd
Unit 69, Carntyne Industrial Estate
Camelon Street
Glasgow
G32 6AF

Report Prepared by:

Anthony Hanson

Identification

Mask Description: Omnitex Procedure Face Masks with ties
 Mask size: 17.5x9.5cm
 Manufacturer: Sharon Services (UK) Ltd
 Customer id: MX-OX-50TB Lot No. 200409
 4ward Sample No: 4863
 Customer reference: email PS/CDC211020
 Date received: 23/10/2020

Test Summary

	M1	M2	M3	M4	M5	threshold	Result
Bacterial filtration efficiency (BFE), [%] 5.2.2	99.81	99.68	99.58	99.74	99.39	≥ 98	Pass
Breathability 5.2.3 (differential pressure) average of 5 areas/mask [Pa/cm ²]	18.16	25.08	24.43	23.32	14.22	< 60	Pass
Splash resistance pressure 5.2.4 [kPa]	31 of 32 masks passed at 16kPa					≥ 29 @16kPa	Pass
Microbial cleanliness 5.2.5 (Bioburden) [cfu/g]	2.41	1.32	0.67	0.94	0.72	≤ 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

Bacterial Filtration Efficiency Section 5.2.2

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

Mean plate counts

Positive controls: 2989 cfu
 Negative control 0 cfu

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

BFE for each test specimen shown in summary table.



Breathability Section 5.2.3

Test area: 4.9±0.4 cm²
 Test quantity: 5 masks
 Test positions: 1 centre, 4 spanning out from the centre
 Test flow rate: 8L/min
 Sample pre-conditioning: 4h @ 21±5°C 85±5%RH

		Mask1	Mask2	Mask3	Mask4	Mask5
Differential pressure [Pa/cm ²]	1	21.79	20.64	25.42	20.83	15.10
	2	16.82	24.27	30.20	23.70	18.35
	3	18.16	26.38	24.08	21.79	10.32
	4	16.82	22.36	19.30	22.74	13.57
	5	17.20	31.73	23.13	27.52	13.76
	Average	18.16	25.08	24.43	23.32	14.22

Splash Resistance Section 5.2.4

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

Centre of mask targeted

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

32 masks Passed

Minimum of 29 Passes required

Microbial Cleanliness Section 5.2.5

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 5 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
Mask Mass [g]	4.56	4.56	4.48	4.25	4.15
Total bioburden (whole mask)	11	6	3	4	3
Bioburden per gram [cfu/g]	2.41	1.32	0.67	0.94	0.72

Date of testing: 29/10-05/11/2020



These results relate only to the samples tested

Work carried out and recorded by the following personnel:



Paula Fountain BSc MSc
Laboratory Technician

Work approved by the following personnel:



Anthony Hanson
Quality Assurance Engineer

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..... **END**

Change log
Corrected manufacturer name

