

JOB NO: 3090

REPORT NO: R2377

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REPORT

On the testing of

Medical Face Masks to EN14683:2019

Supplied by:

MDTI Ltd The Kace Building Victoria Passage Wolverhampton West Midlands WV1 4LG

Report Prepared by:

Anthony Hanson

Identification

Mask Description: KN 95 dome shaped mask

Mask size: 15x10cm (folded)

4ward Sample No: 4698
Customer reference: PO 575
Date received: 18/06/2020

Test Summary

	M1	M2	М3	M4	M5	threshold	Result
Bacterial filtration efficiency (BFE), [%] 5.2.2	100	100	100	100	100	≥ 98	Pass
Breathability 5.2.3 (differential pressure) average of 5 areas/mask [Pa/cm2]	50.41	51.27	55.22	50.69	56.49	< 60	Pass
Splash resistance pressure [kPa]		32 of 32	≥ 16,0	Pass			
Microbial cleanliness 5.2.5 (Bioburden) [cfu/g]	6.39	3.81	4.33	7.27	3.87	≤ 30	Pass

Threshold for type IIR mask

Test Details

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

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: 2786 cfu Negative control 0 cfu

BFE for each test specimen shown in summary table.

Breathability Section 5.2.3

Test area: 4.9 cm²
Test quantity: 5 masks

Test positions: 1 centre, 4 spanning out from the centre

Test flow rate: 8L/min

		m1	m2	m3	m4	m5
Differential pressure [Pa]	1	269	226	213	213	223
	2	270	264	271	266	276
	3	203	247	268	255	264
	4	237	254	242	299	304
	5	256	265	359	209	317
	Average	247	251.2	270.6	248.4	276.8
	Pa/cm ²	50.41	51.27	55.22	50.69	56.49

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 No of Passes 32

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 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

Date of testing: 18.6.2020 - 1.7.2020

These results relate only to the samples tested

Work carried out and recorded by the following personnel:

Paula Fountain BSc MSc Laboratory Technician

L J Komatsu ACQI Technical Manager

Anthony Hanson Quality Assurance Engineer

Work approved by the following personnel:

Anthony Hanson Quality Assurance Engineer

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