EcoTech (Europe) Ltd.
Medical Face Mask Testing

BS EN 14683:2019 Medical Face Masks – Requirements and Test Methods

ISO 11737-1:2018 Determination of a population of microorganisms on products

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Introduction

Test Article: Symsave 3-Ply commercial Facemasks [Disposable Face Mask]
Material Type: Non-woven Polypropylene
LOT/Batch Code: Not Given [GB/T 32610-2016]
Mask Classification: Type I
Purchase Order: 19726
Items Tested: 09/07/2020 – 13/07/2020
Testing Facility: 20/30 Labs Ltd, Unit 6 Osyth Close, Northampton, NN4 7DY
Test Organism (BFE): *Staphylococcus Aureus* ATCC 6538

EcoTech (Europe) Ltd. requested that 20/30 labs carry out bacterial filtration efficacy (BFE), differential pressure (ΔP) and microbial cleanliness (MC) testing of Symsave 3-Ply commercial Facemasks, as per EN14683: 2019.

Bacterial Filtration Efficacy EN 14683: 2019

EQUIPMENT: TE-1-800X Six Stage Ambient Viable Sampler

TEST DATE: 09/07/2020

METHOD:
A sample of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *S. aureus* ATCC 6538 is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Conditioning: 85% ±5 Relative Humidity, 20°C ±2
Test Side: Inside of the mask in contact with the bacterial challenge
Sample Dimensions: 100mm x 100mm
Flow Rate: 28.3L/min
MPS: 3.24µm

ACCEPTANCE CRITERIA:
Samples with a bacterial filtration efficacy ≥95% fulfil criteria for Type I Masks
Samples with a bacterial filtration efficacy ≥98% fulfil criteria for Type II/Type IIR Masks

RESULTS:

Stage No.	R1	R2	R3	R4	R5
C1	0	0	0	2	0
C2	0	1	1	3	0
C3	2	0	0	1	1
C4	7	2	3	0	4
C5	51	66	49	40	45
C6	28	23	30	32	50
SUM (cfu/Sample)	88	92	83	78	100
BFE (%)	95.45	95.24	95.71	95.97	94.83
Mask BFE (%)			**95.44**		

Pressure Differential EN14683: 2019

EQUIPMENT: T438 Pressure differential unit

TEST DATE: 09/07/2020

METHOD:
The pressure differential unit (Model T438) measures the differential pressure required to draw air through a measured surface area at a constant air flow rate and is used to measure the air exchange pressure of the medical face mask material.

Flow Rate: 8L/min

ACCEPTANCE CRITERIA:
Samples with a differential pressure < 40 pascals (Pa/cm^2) fulfil criteria for Type I/Type II Masks
Samples with a differential pressure < 60 pascals (Pa/cm^2) fulfil criteria for Type IIR Masks

RESULTS:

Replicate	Top left	Top Right	Centre	Bottom left	Bottom right	mean ΔP	Mean ΔP/cm2	Mean ΔP/cm2
1	82.8	70.8	86.5	55.2	77.1	74.5	15.2	
2	57.9	72.5	94.4	89.7	87.7	80.4	16.4	
3	61.6	63.2	90.0	91.8	84.9	78.3	16.0	**14.1**
4	58.6	51.5	52.0	59.7	49.0	54.2	11.1	
5	59.6	60.7	55.2	55.0	56.3	57.4	11.7	

Microbial Cleanliness EN11737-1: 2018 / EN14683: 2019

TEST DATE: 13/07/2020

METHOD:
Recovery from the mask/sample(s) is undertaken using a modified, UKAS-accredited method, according to ISO 11737-1: 2018 (Bioburden SOP L053) and as per EN 14683 requirements. Samples are aseptically taken out of packaging in a Class II laminar flow cabinet, weighed and visually examined for any damage. The samples are then placed into 300ml sterile recovery diluent containing a surfactant and sonicated for five minutes. The eluent is tested for viable aerobic bacteria and yeast/moulds on TSA (3 days at 30°C±1) and SDA (7 days at 22°C±2) plates, respectively. The total bioburden is expressed by addition of the TSA and SDA cfu counts at the end of the incubation period.

Method Deviation: Samples are aseptically placed in sterile stomacher bags and not 500ml bottle stipulated in EN14683: 2019.

ACCEPTANCE CRITERIA:
Samples with a microbial cleanliness ≤ 30 (cfu/g) fulfil the criteria for Type I/Type II and Type IIR Masks.

RESULTS:

Mask Weight (g)	TSA (cfu)	SDA (cfu)	Total Bioburden (cfu/mask)	Total Bioburden (cfu/g)
2.912	40	5	45	23.18
3.140	22	2	24	11.46
3.010	25	2	27	13.46
3.110	10	3	13	6.27
3.004	15	4	19	9.49
		Mean:	**25.6**	**12.77**

NOTE: The recovery efficiency satisfies ISO 11737-1:2018 requirements that a minimum of 50% of organisms known to be present are detected by the test method.

Conclusion

Symsave 3-Ply commercial Facemasks [Disposable Face Mask] provided by EcoTech (Europe) Ltd. were tested for Bacterial Filtration Efficacy and Differential Pressure as per EN14683 and Microbial Cleanliness as per ISO 11737-1: 2018 and as per EN14683 requirements. The mask performed as follows;

bacterial filtration efficacy ≥95%

differential pressure < 40 pascals (Pa/cm^2)

microbial cleanliness ≤ 30 (cfu/g)

Symsave 3-Ply commercial Facemasks [Disposable Face Mask] fulfils the performance requirements criteria for a Type I Medical Face Mask as per EN14683.

Tested/Authorised by:

Tested By:

Joseph Fitzsimons

Research Scientist

Tested and Authorised By:

James Clarke

Head of Scientific Innovations

20/30 Labs Ltd is UKAS accredited to ISO 13485 accredited for; “The provision of microbiological testing and consultancy for the medical device industry. Research, microbiological evaluation and decontamination validation of medical devices”. The results detailed in this test report only pertain to the sample[s] supplied, tested in accordance with ISO 13485 protocol using reasonable skill and care.

All concluding remarks, recommendations and results contained in this report are submitted in good faith. However, other than as expressly set out in this report, no warranty is given (i) in relation to the testing or the use[s] to which any results or deliverables produced in the course of the testing are or may be put by the client or their fitness or suitability for any particular purpose or under any special conditions notwithstanding that any such purpose or conditions may have been known to 20/30 Lab Ltd or (ii) that the intended results or deliverables from the testing can be achieved or (iii) that the client can freely make use of the results or the deliverables without infringing any third party intellectual property rights and the client will be deemed to have satisfied itself in this regard.