TEST REPORT NO: 164272B (Replaces 164272A)

Date:30 September 2020

(Original report dated 26 August 2020)

ORVEC INTERNATIONAL LTD
MALMO ROAD, SUTTON FIELDS IND ESTATE
HULL
EAST YORKSHIRE
HU70YF
UNITED KINGDOM

The following sample(s) was/were submitted and identified by/on behalf of the client as:

Retailer	PPE Testing
Description of article	TYPE IIR FACE MASK
Retailer style number	BLUE
Lot No. / Batch	UNKNOWN
Order No./ Buyer	DA290720
Quality/Fibre Composition	3 LAYER NON WOVEN PP CONSTRUCTION
Date Sample(s) Received:	31 July 2020 & 07/09/2020

Tests	Pass	Fail	Remarks
EN14683 Type IIR Medical Face Masks (Excluding Clause 6)	X		

Signature

M. Harrison

M. Harrison Laboratory Manager

For and on behalf of
SGS United Kingdom Ltd

All samples are conditioned to ISO 139 where conditioning is required (unless otherwise stated)

(Report 164272A supersedes report 164272 dated 26 August 2020, correction to typing error on page 2)
(Report 164272B supersedes report 164272A dated 27 August 2020, Microbial Cleanliness retested on additional samples received on 07th September2020)

Customer:	**ORVEC INTERNATIONAL LTD**	**Test Report No:**	**164272B (Replaces 164272A)**

Test Results

EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods

Scope: This document specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.

Number of specimen: 120pcs of complete product

Clause	Test Items/requirement	Test Result summary
5	**Requirements**	
5.1	**General**	
5.1.1	Materials and construction	PASS The mask is composed of a filter layer that is bonded between layers of fabric. The mask was not disintegrated, split or tear during intended use, and no objectionable matter was observed by visual assessment.
5.1.2	Design	PASS Length: 17.5 cm Width: 9.5 cm (Folded): 16.3 cm (Expanded)
5.2	**Performance requirements**	
5.2.2^	Bacterial filtration efficiency (BFE)	>98%
5.2.3^	Breathability (Differential Pressure)	<60 Pa/cm^2
5.2.4	Splash resistance	Penetration not seen at 16.0 kPa
5.2.5	Microbial cleanliness (Bioburden)	<30cfu/g
5.2.6	Biocompatibility	Not Conducted as per client request
5.2.7	Summary of performance requirements	See Table 1
6	**Marking, labelling and packaging**	Not Conducted as per client request

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Table 1 Performance requirements for medial face masks

Characteristics	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), %	≥95	≥98	≥98
Differential pressure, Pa/cm^2	<40	<40	<60
Splash resistance (kPa)	Not required	Not required	≥16.0
Microbial cleanliness (cfu/g)	≤30	≤30	≤30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.
An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

Note:
^ Results of compliance for tests requested is justified according to decision rule based on the non-binary statement with guard band (is equal to the expanded measurement uncertainty with a 95% coverage probability, w = U_{95}) as stated in ILAC-G8:09/2019 Clause 4.2.3.
"Pass – The measured values were observed in tolerance at the points tested. The specific false accept risk is up to 2.5%."
"Fail – One or more measured values were observed out of tolerance at the points tested". The specific false reject risk is up to 2.5%

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Test Results

Result 1 Bacterial filtration efficiency (BFE) (EN14683:2019+AC:2019 Appendix B)

Test Side : White colour (Inside)
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H
Dimensions of the test specimen : 175 mm x 94 mm
BFE Test Area : 49cm^2
BFE Flow Rate : 28.3 l/min
Test bacteria : Staphylococcus aureus ATCC 6538
Positive Control Average : 2.0 x 10^3 CFU
Negative Monitor Count : < 1 CFU

Test Specimen	Percent BFE (%)
1	99.9
2	99.8
3	99.8
4	99.9
5	99.8

Result 2 Determination of Breathability (EN14683:2019+AC:2019 Appendix C Differential pressure)

Test Side : White colour (Inside)
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H
Test Area : 4.9cm^2
Flow Rate : 8 l/min

Test Location	ΔP (Pa/cm^2)				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	41.4	43.7	45.7	43.8	43.2
Centre	44.0	41.4	42.8	45.1	47.0
Bottom Centre	41.4	38.9	36.8	40.1	39.4
Centre Left	40.8	48.0	42.2	40.5	44.0
Centre Right	39.5	38.7	39.1	38.7	34.3
Average	41.4	42.1	41.3	41.6	41.6

Result 3 Splash resistance (ISO 22609:2004)

Test Side : Blue colour (Outside)
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H
Test Conditioning : 21±5°C and (85±10%) R.H
Test Pressure : 16.0 kPa (120 mmHg)
No of Test Specimen Tested : 32
No of Test Specimen Passed : 32

Test Specimen #	Synthetic Blood Penetration
1-32	None seen

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Result 4 Microbial cleanliness (Bioburden) (EN 14683:2019+AC:2019 Annex D)

Test Methods* carried out on additional sample received
Bioburden
The analyses were performed according to EN 14683:2019+AC:2019 Annex D and ISO 11737-1:2018

TYPE IIR FACE MASKS

Article Number	Mask Weight	Total Bioburden cfu/mask	Total Bioburden, cfu/g
1	3.33g	3	0.90
2	3.38g	<3	<0.89
3	3.36g	3	0.89
4	3.31g	3	0.91
5	3.43g	6	1.75
	Mean:	<3.6	<1.1

Recovery Efficiency	Correction Factor
93.1%	1.1

Microbial Cleanliness (Bioburden): <1.1 cfu/g

Standard requirement#: ≤30 cfu/g

Note:
1. Results reported on the submitted sample on an as received basis
2. < = less than
3. cfu = Colony Forming units
4. Extraction method; by stomacher at 250rpm for 5 minutes
5. # EN 14683:2019+AC:2019 – Medical face masks – Requirements and test methods – Performance requirements for medical face masks – Microbial cleanliness

*Sub contracted to an SGS ILAC-MRA IAS accredited lab

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Test Results

End of Report