TEST REPORT NO: 163887A (Replaces 163887)

Date: 17 September 2020

(Original report dated 12 August 2020)

HOMESHIELD PRODUCTS LTD
UNIT 13 PHOENIX WORKS
VERNON ROAD
NOTTINGHAM
NG6 0AT
UNITED KINGDOM

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

Retailer	PPE Testing
Description of article	IIR 3ply Non-Sterile Disposable Surgical Face Mask
Retailer style number	Blue
Retailer Standard Number	Unknown
Order No./ Buyer	Abraze
Quality/Fibre Composition	Meltblown/Non-Woven Spun Bouna
Date Sample(s) Received:	16 July 2020

Tests	Pass	Fail	Remarks
EN14683 Type IIR Medical Face Masks	X		

Signature

For and on behalf of
SGS United Kingdom Ltd

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

(Report 163887A supersedes report 163887 dated 12 August 2020, retest on microbial cleanliness and new packaging sent for Clause 6 testing)

Customer:	**HOMESHIELD PRODUCTS LTD**	**Test Report No:**	**163887A (Replaces 163887)**

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: 220pcs 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: 17.4cm cm Width: 9.4 cm (Folded): 15.6 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)	< 30 cfu/g
5.2.6	Biocompatibility	Not Conducted as per client request
5.2.7	Summary of performance requirements	See Table 1

Customer:	**HOMESHIELD PRODUCTS LTD**	**Test Report No:**	**163887A (Replaces 163887)**

Test Results

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%

Customer:	**HOMESHIELD PRODUCTS LTD**	**Test Report No:**	**163887A (Replaces 163887)**

Test Results

Clause	Test Items/requirement	Test Result Summary
6	Marking, labelling and packing	PASS
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Devices Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical mask is supplied. The following information shall be supplied: a) Number of this European Standard: b) Type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered	See Note

Customer: HOMESHIELD PRODUCTS LTD

Test Report No: 163887A (Replaces 163887)

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 : 174 mm x 93 mm
BFE Test Area : 49cm^2
BFE Flow Rate : 28.3 l/min
Test bacteria : Staphylococcus aureus ATCC 6538
Positive Control Average : 2.3 x 10^3 CFU
Negative Monitor Count : < 1 CFU

Test Specimen	Percent BFE (%)
1	99.6
2	99.6
3	99.6
4	99.7
5	99.6

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	35.7	35.5	36.3	38.6	34.2
Centre	43.0	33.3	39.2	38.3	46.4
Bottom Centre	42.9	48.5	40.5	44.7	47.5
Centre Left	36.4	44.4	31.7	49.2	42.8
Centre Right	34.9	39.1	35.4	41.6	39.7
Average	38.6	40.2	36.6	42.5	42.1

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
No of Test Specimen Tested : 32
No of Test Specimen Passed : 31

Test Specimen #	Synthetic Blood Penetration
1-18. 20-32	None seen
19	Yes

Customer: HOMESHIELD PRODUCTS LTD

Test Report No: 163887A (Replaces 163887)

Test Results

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

Test Methods
Bioburden
The analyses were performed according to EN 14683:2019+AC:2019 Annex D and ISO 11737-1:2018

TYPE IIR, Non-Sterile Mask

Article Number	Mask Weight	Total Bioburden cfu/mask	Total Bioburden, cfu/g
1	3.17g	18	5.68
2	3.21g	30	9.35
3	3.18g	15	4.72
4	3.13g	9	2.88
5	3.18g	<3	<0.94
	Mean:	<15	<4.7

Recovery Efficiency	Correction Factor
60.1%	1.7

Microbial Cleanliness (Bioburden): <7.8 cfu/g

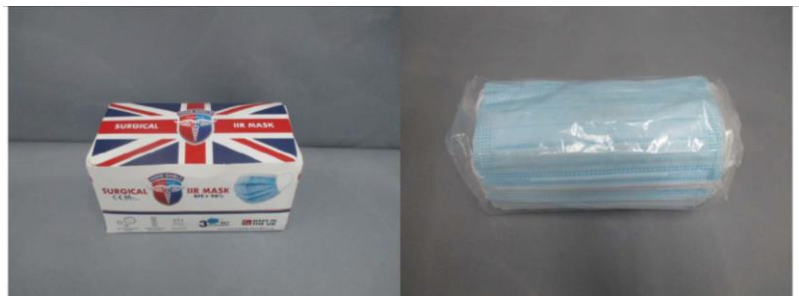
Standard requirement#: ≤30 cfu/g

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 a ilac-MRA & IAS (TL-817) accredited lab

Customer:	**HOMESHIELD PRODUCTS LTD**	**Test Report No:**	**163887A (Replaces 163887)**

Test Results



End of Report