FTNR.MM01

Test Date	21/09/2022
Issue Date	27/09/2022
Report Number	40039A
Revision	1
Client Work Order	Not Provided

MEDICAL MASK TESTING REPORT - AS 4381:2015

CUSTOMER REFERENCE:

Advanced Medical Devices (AMD) Pty Ltd

CUSTOMER ADDRESS:

C-1, 107 Erskine Park Road, Erskine Park NSW 2759

CUSTOMER REPRESENTATIVE:

Peter Lee

MASK REFERENCE

N4HS

BATCH NUMBER:

AE120922L

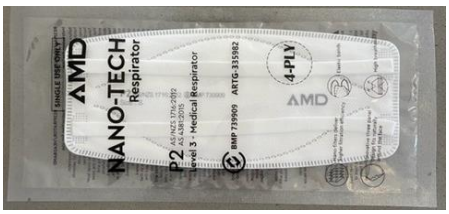
MANUFACTURE DATE:

12/09/2022

SAMPLE RECIEPT DATE:

19/09/2022

Sample Details (including construction materials)
Mask is a single use medical respriator - Level 3
Structure consists of a 4-ply nano filter composition with three panels and elastic hand bands
BMP 739909 ARTG-335982
Sample Numbers: FTN22003-1 thru FTN22003-32



Revision	Date	Technician	Revision Details
1	21/09/2022	M.Brack	Initial Testing

The results shown and information given in this report are certified to be accurate and complete to the extent by equipment and procedure used on this date

Testing Technician Details:	Matthew Brack	Technician Signature:	MB	Date of Test:	21/09/2022
Authorised Signatory Details:	Kieg Simpson	Signatory Signature:		Date of Review:	27/09/2022

All testing performed at Flowtech, 1/54 Nealdon Drive, Meadowbrook, QLD

Accredited for compliance with ISO/IEC 17025 - Testing. Accreditation number: 19187

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EN 14683:2014 Annex B — METHOD FOR *IN-VITRO* DETERMINATION OF BACTERIAL FILTION EFFICIENCY (BFE)

SECTION 1: TEST OBJECTIVE, STANDARD OF ACCREDITATION & COMPLIANCE

1.1 TEST OBJECTIVE:

This test method is used to measure the bacterial filtration efficiency of medical masks

1.2 STANDARD OF ACCREDITATION & PERFORMANCE CRITERIA

Test Method		Performance Criteria
EN 14683:2014 Annex B	Method for *in-vitro* determination of bacterial filtration efficiency (BFE)	AS 4381:2015 - Section 5.2: Level 3 Barrier Protection, the bacterial filtration efficiency of the mask shall be ≥ 98%

1.3 ACCEPTABLE QUALITY LEVEL

The data presented in the following table is provided to assist dermination of conformity where the minimum test sample numbers are adopted from ISO 22609 and EN 14683:2014

AQL	Samples tested	Maximum number of non-conforming samples allowed for lot to be accepted
4%	5	0
	32	4

In order to conform with ISO 22609 and EN 14683:2014 (Annex C), an acceptable quality limit (AQL) of 4% must be achieved, for example in accordance with AS 1199.1/ISO 2859-1. Flowtech are unable to make any assessment of AQL based upon the results detailed in this report as the information relating to production lots/batches and associated sampling plans are not provided. Based on the production circumstances and the relevant sampling conditions, it remains the responsibility of the submitting entity to assess whether the results detailed in this report are sufficient in establishing a suitable AQL for this particular production lot/batch.

SECTION 2: TEST REPORT & PROCEDURES

2.1 SPECIMEN DETAILS AND TEST CONDITIONS

Test Specimen Dimension	Size of Area Tested	Challenge Orientation	Flow Rate During Testing
100 x 100 mm	80 mm diameter	Inside of mask in contact with bacterial challenge	28.3 L/min

2.2 TEST CONTROLS

Test Control	Test Count (CFU)	Positive Control Average (CFU)	Mean Particle Size (µm)
Positive Control 1	2124	2151	2.92
Positive Control 2	2177		2.84
Negative Control	0	N/A	N/A

2.3 TEST RESULTS

Sample Number	Test Count (CFU)	Bacterial Filtration Efficiency (%)	Measurement Uncertainty (%)[1]
FTN22003-1	1	99.95	0.231
FTN22003-2	1	99.95	0.231
FTN22003-3	<1	>99.99	0.231
FTN22003-4	<1	>99.99	0.231
FTN22003-5	1	99.95	0.231
FTN22003-6	<1	>99.99	0.231
FTN22003-7	2	99.91	0.231
FTN22003-8	1	99.95	0.231
FTN22003-9	2	99.91	0.231
FTN22003-10	<1	>99.99	0.231
FTN22003-11	<1	>99.99	0.231
FTN22003-12	<1	>99.99	0.231
FTN22003-13	2	99.91	0.231
FTN22003-14	1	99.95	0.231
FTN22003-15	1	99.95	0.231
FTN22003-16	<1	>99.99	0.231

Test results continued on page 3

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EN 14683:2014 Annex B — METHOD FOR *IN-VITRO* DETERMINATION OF BACTERIAL FILTION EFFICIENCY (BFE)

2.3 TEST RESULTS *(Continued)*

Sample Number	Test Count (CFU)	Bacterial Filtration Efficiency (%)	Measurement Uncertainty (%)[1]
FTN22003-17	1	99.95	0.231
FTN22003-18	<1	>99.99	0.231
FTN22003-19	<1	>99.99	0.231
FTN22003-20	<1	>99.99	0.231
FTN22003-21	1	99.95	0.231
FTN22003-22	<1	>99.99	0.231
FTN22003-23	2	99.91	0.231
FTN22003-24	1	99.95	0.231
FTN22003-25	3	99.86	0.231
FTN22003-26	3	99.86	0.231
FTN22003-27	<1	>99.99	0.231
FTN22003-28	<1	>99.99	0.231
FTN22003-29	3	99.86	0.231
FTN22003-30	<1	>99.99	0.231
FTN22003-31	<1	>99.99	0.231
FTN22003-32	2	99.91	0.231

[1] The stated expanded measurement uncertainty is given for coverage factor (k) = 2, 95% confidence interval

The items detailed in this report pass the performance criteria in accordance with the following decision rule:
1) Where the upper limit of the bacterial filtration efficiency (%) result plus the measurement uncertainty is greater than the acceptance criteria, the sample is reported as a pass.
2) Where the upper limit of the bacterial filtration efficiency (%) result plus the measurement uncertainty is less than the acceptance criteria, the sample is reported as a fail.

2.4 TEST SUMMARY

Performance Criteria	Total Specimens Tested	Total Conforming Specimens	Total Non-Conforming Speciemns	Overall Result
AS 4381:2015 - Section 5.2: Level 3 Barrier Protection, the bacterial filtration efficiency of the mask shall be ≥ 98%	32	32	0	Pass

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