

Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD

3/4 - 8 Inglewood Place,

Baulkham Hills NSW 2153 Australia

Test Report Number:

221235

Testing Requested By:

Arihiro Yamada

Client's Order Number: Not Supplied

Date Samples Received:

12/01/2023

Date Testing Completed:

19/01/2023

Factory 5 -7/ 383 Dorset Road Boronia, Victoria Australia 3155

Bayswater, Victoria, Australia Telephone: +61 3 9761 0766 Email: viclab@bigpond.com

P.O. Box 517

Sample Description:

N4HL, Large, Single use, Trifold particulate respirator, Twin head loops, Internal metal nose clip, Individually wrapped, Marking printed: P2 AS 4381:2015, BMP 739909, N4HL, Size L, AMD, Expiry 01/11/2025, Batch Number: AE:01.11.22HLSamples as supplied.



Testing Requested:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as required by AS 4381:2015 using Test method ISO 22609



Legend: NA = Not Applicable NT = Not Tested NS = Not Supplied TBA = To Be Ascertained

Document name: Differential Pressure

A2LA Accredited Laboratory Certificate Number 6187.01

Accredited for compliance with ISO/IEC 17025 - Testing

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R. A. Vickery



Test Report Number:

221235

Factory 5 -7/ 383 Dorset Road Boronia, Victoria Australia 3155

P.O. Box 517 Bayswater, Victoria, Australia

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Summary of Testing and Results:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as per ISO 22609

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as per ASTM F1862/F1862M-17

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862/F1862M-17 and ISO 22609 (as referenced in AS 4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 °C \pm 5°C and a relative humidity of 85 \pm 10%. Test specimens were tested in ambient conditions within one minute of removal from the conditioning chamber.

Samples Pre-Conditioned at 21 ± 5°C and 85 ± 10% relative humidity for a minimum of 4 hours prior to testing.

Test Conditions: 21.5°C, R.H.69%

Test pressure: 21.3 kPa

General location of the areas of the mask specimens target area: Central area of mask (Zone 1) General location of the areas of the mask specimens target area: Printed Logo (Zone 2) General location of the areas of the mask specimens target area: Top Seam (Zone 3) General location of the areas of the mask specimens target area: Bottom Seam (Zone 4)

Was targeting-plate method used: Yes



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Test Report Number:

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Summary of Testing and Results:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as per ISO 22609 continued.

Specimen Number	Synthetic Blo	od Penetration (Z	Result mm Hg	Pass/Fail		
Zone tested	1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2	3	4		
1	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
2	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
3	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
4	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
5	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
6	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
7	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
8	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
9	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
10	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
11	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
12	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
13	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
14	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
15	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
16	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
17	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
18	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
19	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
20	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
21	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
22	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
23	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
24	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
25	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass



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Summary of Testing and Results:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as per ISO 22609 continued.

Specimen Number	Synthetic Blo	od Penetration (Z	Result mm Hg	Pass/Fail		
Zone tested	1	2	3	4		
26	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
27	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
28	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
29	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
30	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
31	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass
32	None Seen	None Seen	None Seen	None Seen	160 mm Hg	Pass

Highest pressure corresponding to a stream velocity for which an acceptable quality limit of 4.0% -

Samples supplied have achieved Level 3 Barrier Resistance to penetration by synthetic blood requirement.

Resistance to penetration	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
by synthetic blood, minimum pressure in	80 mm Hg	120 mm Hg	160 mm Hg
mm Hg requirement as per AS 4381:2015			

Test Uncertainty:

These uncertainty values are based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95% - Uncertainty of measurement has not been taken into account when presenting the test result.



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