

Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD  
 c/of C-1, 107 Erskine Park Road  
 Erskine Park  
 NSW 2759

Test Report Number: 220946

Testing Requested By: Frank Galluzzo

Client's Order Number: Not Supplied

Date Samples Received: 19/09/2022

Date Testing Completed: 14/10/2022

Sample Description: Model N4HS, Batch Number: AE120922L, Marking Printed: P2 AS/NZS 1716:2012, BMP 739909, Size S, AMD, EXP: 120925L, 50 pieces individually wrapped, Single use only, Half facepiece, Tri-fold particulate respirator, Internal metal nose clip, Twin head loop, Samples as supplied.



Testing Requested: Class P2  
 AS/NZS 1716:2012 – Respiratory Protective Devices, Section 2 – Design and Construction of Assembled Respirators, Clauses 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.2.1 and 2.2.2 (Appendix D – Total Inward Leakage of Assembled Respirators – Quantitative Sodium Chloride Test)  
 AS/NZS 1716:2012 – Respiratory Protective Devices, Section 3 – Facepieces Head Coverings and Harnesses  
 AS/NZS 1716:2012 – Respiratory Protective Devices, Section 4 – Particulate Filter Respirators



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*R.A. Vickery*



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### Pre-Conditioning Summary

Pre-conditioning as per clause 4.3.1 whereby whole filter assembly has been tested and Clause 1.6 has been applied.

### Summary

Clause	Page Number	Compliance/Non-Compliance
2.1.1	3	Compliance
2.1.2	3	Compliance
2.1.3	4	Compliance
2.1.4	4	Compliance
2.2.1	5	Compliance
2.2.2	6	Compliance
3.1.1	7 and 8	Compliance
3.1.4	9	Compliance
3.2.1	9	Compliance
3.2.5	10	Compliance
3.2.6	10	Compliance
4.1	11	Compliance
4.2.1	12	Compliance
4.2.3	12	Compliance
4.3.2	12	Compliance
4.3.3	13	Compliance
4.3.4	13	Compliance
4.3.5	14	Compliance
4.3.6	14	N/A
Annex A – Appendix D	15	Compliance

#### 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.

NOTE: Samples supplied comply with P2 requirements of AS/NZS 1716:2012 for the clauses tested.



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AS/NZS 1716:2012 – Respiratory Protective Devices, Section 2 – Design and Construction of Assembled Respirators, Clauses 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.2.1 and 2.2.2

Requirement	Result	Compliance / Non-Compliance
<b>2.1 General Requirements</b>		
<b>2.1.1 Assembled respirators</b>		
Assembled respirators shall be made up of components which have been tested together as a system.	Complies	Compliance
The apparatus shall be constructed from durable components	Durable	Compliance
The vital parts of the apparatus shall be protected so as to prevent damage and excessive wear during normal use.	Protected	Compliance
All parts shall be finished smooth and free from sharp edges and from irregularities that could be a potential hazard or cause discomfort to the wearer.	Smooth	Compliance

Requirement	Result	Compliance / Non-Compliance
<b>2.1.2 Materials</b>		
Respirators should be made of materials able to withstand storage and usage in environments that are likely to be encountered.	Complies	Compliance
Materials which may come in contact with the skin should be:		
- Non-staining	Non-staining	Compliance
- Soft	Soft	Compliance
- Pliable	Pliable	Compliance
- Not likely to cause skin irritation	Not likely to cause skin irritation	Compliance
- Shall not taste or smell offensive	Does not taste or smell offensive	Compliance
Material from the filtering medium released by air flowing through the filter shall not constitute a hazard or nuisance to the wearer.	Complies	Compliance


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Requirement	Result	Compliance / Non-Compliance
<b>2.1.3 Filters</b>		
Where appropriate, filters shall be readily replaceable without requiring the use of special tools	Single use Readily replaceable	Compliance
Shall be designed or marked to prevent incorrect assembly.	One piece	Compliance
When the filter is designed to be used with a twin filter facepiece only it shall not be possible to connect the filter to a single filter facepiece unless, by doing so, the respirator assembly would also comply with the requirements for a single filter respirator.	-	N/A
The particulate filter of a combined gas and particulate respirator shall be on the influent side of the gas filter.	-	N/A
The mass of the replacement filter (or filters) shall not exceed -	-	N/A
(a) 300g when it is to be directly connected to a half facepiece; and	-	N/A
(b) 500g when it is to be directly connected to a full facepiece.	-	N/A

Requirement	Result	Compliance / Non-Compliance
<b>2.1.4 Shelf Life</b>		
Each component part of the respirator should have a nominal shelf life of at least five years when properly stored, unless otherwise specified by the manufacturer.	Specified by manufacture	Compliance


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Requirement	Result	Compliance / Non-Compliance
2.2 Facial Fit		
2.2.1 General		
Facial fit of complete respirators shall be tested by determining the total inward leakage of the respirator by a test aerosol of sodium chloride according to the method described in Appendix D.	Complies Size Small A	Compliance
Personnel shall be selected in accordance with Appendix B. Where the fit of a respirator to a particular physiognomy, whether it be characterized by size or specific facial features, is to be assessed, the testing laboratory, may select test personnel who conform to that physiognomy. Where testing has been carried out in this manner, the manufacturer shall label the respirator accordingly. See Clause 12.1.2.2.	Personnel selected for physiology A	Compliance
When carrying out the test procedure, none of the wearer shall experience any undue discomfort on account of:		
- The fit	Complies	Compliance
- Air delivery	Complies	Compliance
- Any other feature of the respirator	Complies	Compliance
Alternative methods of determining total inward leakage, e.g. using sulfur hexafluoride, may be accepted by the test authority where a correlation with these methods and test criteria has been shown.	-	N/A



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Requirement	Result	Compliance / Non-Compliance
<b>2.2.2 Assessment</b>		
Total inward leakage (TIL) of assembled respirators when tested in accordance with Appendix D shall be assessed for compliance with Table 2.1	Complies Refer Annex A	Compliance
Half facepiece respirators shall be tested with the highest efficiency filters.	-	N/A
Full facepiece respirators of the non-powered type shall be tested with either P3 filter or a simulated filter blank.	-	N/A
If any test subject records a mean inward leakage for any one test in excess of that specified in Column 2 of Table 2.1, or if the mean of the results of an individual test subject exceeds that specified in Column 1 of Table 2.1, the respirator shall be deemed not to comply with this intended class, or have failed	-	N/A
Where the respirator is supplied in more than one size, the test subject shall be supplied with the appropriate size. Any test subject whose maximum inward leakage exceeded that specified in Table 2.1 may participate in further test using an alternative size of the same respirator.	-	N/A

**Table 2.1**  
Maximum Total Inward Leakage (TIL) per Test Subject

Respirator	Percent total inward leakage	
	Mean result of test subject not to exceed	No individual exercise result to exceed
<b>Non-powered</b>		
- Half face piece		
Class P1 filters	22.0	22.0
Class P2 filters	8.0	8.0
- Full facepiece		
Class P3	0.05	0.05
<b>Powered</b>		
Class PAPR P1 Filters	5.0	5.0
Class PAPR P2 Filters	1.0	1.0
Class PAPR P3 Filters	0.05	0.05
<b>Air-supplied</b>		
Continuous flow	0.02	0.05
Positive pressure demand	0.02	0.05



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## Results:

AS/NZS 1716:2012 – Respiratory Protective Devices, Section 3 – Facepieces Head Coverings and Harnesses

Requirement	Result	Compliance / Non-Compliance
<b>3.1 DESIGN REQUIREMENTS</b>		
<b>3.1.1 GENERAL</b>		
Each facepiece or head covering shall comply with the following:		
(a) Be designed to fit a wide range of facial contours and head sizes of the workplace population	Size S	Compliance
(b) Be supported on the head or shoulders by suitable means so that the device remains in position during normal work practices, especially when the wearer bends forward from the waist	Remains in position	Compliance
(c) Permit the component parts likely to require service to be readily detached for maintenance and cleaning, but be secure against accidental disconnection.	-	N/A
(d) Where the head covering has been designated by the manufacturer as being suitable for abrasive blasting, the construction shall provide physical protection to the wearer's head, shoulders and upper part of the chest against rebounding abrasives.	-	N/A
Helmets fitted with a visor which is supported in a hinged frame shall have a means for securely fastening the frame in its closed position so that it cannot be opened inadvertently.	-	N/A



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Results:

AS/NZS 1716:2012 – Respiratory Protective Devices, Section 3 – Facepieces Head Coverings and Harnesses

Requirement	Result	Compliance / Non-Compliance
(e) Where an inner bib is proved as part of the head covering, it shall be of a material which will prevent or restrict the flow of air through it	-	N/A
The bib may have a drawstring or elasticized neck band or cuff to draw the bib closely around the wearers neck	-	N/A
The hood or bib shall be readily removable for cleaning or replacement.	-	N/A
The design of the facepiece or head covering should cause the least possible interference with speech and vision.	Complies	Compliance
The full facepiece should be designed to minimize misting of the face mask, e.g. by provision of orinasal inserts or nose cups. It should also permit the use of special spectacles designed for use without temple pieces, so that air tightness is not affected.	-	N/A
Full facepieces should incorporate facilities for speech transmission. The components of any electrically operated speech transmission device shall be 'intrinsically safe' or 'flameproof' (see Clause 2.1.7) if they are to be used in flammable atmospheres.	-	N/A
Where the use of the apparatus is intended solely for escape, a mouthpiece an nose clip may be incorporated in place of a facepiece	-	N/A



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AS/NZS 1716:2012 – Respiratory Protective Devices, Section 3 – Facepieces Head Coverings and Harnesses

Requirement	Result	Compliance / Non-Compliance
<b>3.1.4 Nose Clip</b>		
The nose clip shall be designed so as to effect the maximum possible security against displacement or slipping, for example, if the wearer receives a chance blow, or stumbles, or their nose becomes wet with perspiration	Complies	Compliance
Suitable means shall be provided for attaching the nose clip to the mouthpiece	Suitable	Compliance
The nose clip shall be so positioned that, when inserting the mouthpiece, the user is made aware of the need to apply the nose clip	Complies	Compliance

Requirement	Result	Compliance / Non-Compliance
<b>3.2 Performance Requirements</b>		
<b>3.2.1 Facial fit</b>		
In combination with other components, e.g. filters and air supply, the assembled respirator shall provide adequate protection either by means of a facial seal or by the provision of positive pressure in the space enclosed by the respirator, or by both, to minimize the entry of ambient atmosphere	Complies	Compliance
Facial fit of complete respirators shall be tested by determining the total inward leakage in accordance with Clause 2.2	Complies	Compliance



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## Results:

## AS/NZS 1716:2012 – Respiratory Protective Devices, Section 3 – Facepieces Head Coverings and Harnesses

Requirement	Result	Compliance / Non-Compliance
3.2.4.2 Exhalation valve leakage		
The exhalation valve or fitting surface of the facepiece shall be sealed to a former and, where appropriate, the inlet air opening of the facepiece sealed.	-	N/A
When tested with air at a constant suction head of 250Pa, the leakage into the facepiece from the valve or valves and any leakage as appropriate from around the eyepiece or visor shall not exceed 30 mL/min.	-	N/A
During the test, both valve(s) and seating shall be free of moisture	-	N/A

Requirement	Result in Pa					Compliance / Non-Compliance
	Sample Number					
3.2.5 Exhalation resistance – Air filtering respirators	1	2	3	4	5	
When tested in accordance with Appendix G at a continuous flow rate of $85 \pm 2$ L/min, the exhalation resistance of the entire assembly, measured relative to the static pressure in the facepiece, shall be less than or equal to-						
(a) For all full facepieces.....200 Pa	-	-	-	-	-	N/A
(b) For all half facepieces.....120 Pa	62	48	51	66	57	Compliance



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AS/NZS 1716:2012 – Respiratory Protective Devices, Section 4 – Particulate Filter Respirators

Requirement	Result	Compliance / Non-Compliance
<b>3.2.6 Security of attachments</b>		
Fittings directly attached to the head covering or facepiece including filter receptacles, exhalation valve housing, speech diaphragms and demand valves but excluding straps and buckles shall be tested accordingly for security of attachment as applicable when assembled in accordance with the manufacturer's instructions		
Each such attachment shall withstand an axial tensile force of 50N for 10s	-	N/A
Each strap, buckle and its attachment to a half facepiece shall withstand an axial tensile force of 10 N applied for 10s in the direction of pulling when the facepiece is fitted.	Complies	Compliance

Requirement	Result	Compliance / Non-Compliance
<b>4.1 Design and Construction</b>		
The design and construction of a particulate filter shall be such that, when combined or incorporate with the appropriate facepiece or head covering it shall provide protection against particulates in accordance with its class.		
The respirator shall be designed so that all the inhaled air passes through the filter or filters.	Complies	Compliance
Particulate filter respirators shall comply with Sections 2, 3 and 12, as appropriate. A filter shall comply with Clause 4.3	Section 2 Section 3 Section 12	Compliance Compliance BSI Certified Product



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## AS/NZS 1716:2012 – Respiratory Protective Devices, Section 4 – Particulate Filter Respirators

Requirement	Result	Compliance / Non-Compliance
<b>4.2 Classification and Components</b>		
<b>4.2.1 Classes</b>		
Three classes of particulate filter are differentiated according to filtering efficiency:		
(a) Class P1 – intended for use against mechanically generated particulates of sizes most commonly encountered in industry.	-	N/A
(b) Class P2 – intended for use against both mechanically and thermally generated particulates.	P2 complies	Compliance
(c) Class P3 – intended for use against all particulates including highly toxic materials	-	N/A

Requirement	Result	Compliance / Non-Compliance
<b>4.2.3 Components</b>		
The respirator shall include a particulate filter complying with Clause 4.3	Complies	Compliance
It may incorporate -		
(a) A full or half facepiece, a head covering, or a mouthpiece held securely in position by a head harness;	Half facepiece	Compliance
(b) An exhalation valve or exhalation valve assembly;	-	N/A
(c) An inhalation valve or inhalation valve assembly;	-	N/A
(d) One or more filter holders;	-	N/A
(e) One or more flexible breathing tubes;	-	N/A
(f) A belt or harness to attach the filter or filters to the wearer's body; and	-	N/A
(g) A gas and vapour filter complying with Clause 5.4	-	N/A



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Requirement	Result	Compliance / Non-Compliance
<b>4.3.2 Simulated Rough Usage – Appendix H</b>		
At the conclusion of the test, the filters shall show no visible deterioration.	No visible deterioration	Compliance
<b>4.3.3 Simulated Wear Treatment</b>		
Respirators except PAPR which have no exhalation valve, or where a substantial proportion of the exhaled air passes back through the filter, shall be subject to exhaled air humidity pre-conditioning in accordance with Paragraph E5.6 of Appendix E.	Subjected	Compliance
If filters are not tested directly upon completion of such pre-conditioning, they should be stored in a manner so as to retain their humidity prior to testing for filtering efficiency.	Sealed bag	Compliance

Requirement	Result in Pa Sample Number					Compliance / Non-Compliance
<b>4.3.4 Inhalation resistance</b>						
When tested in accordance with Appendix G with a continuous stream of air passing through the assembly at a defined rate, the resistance imposed by the assembly shall not exceed the values given in Table 4.1						
	1	2	3	4	5	
at 30 ± 1 L/min	11	11	13	13	10	Compliance
at 95 ± 2 L/min	53	54	60	63	68	Compliance

TABLE 4.1  
INHALATION RESISTANCE

Filter class	Filter assembly only maximum resistance, Pa*		Assembled respirator maximum resistance, Pa*	
	At 30 ± 1 L/min	At 95 ± 2 L/min	At 30 ± 1 L/min	At 95 ± 2 L/min
P1	60	210	110	340
P2	70	240	120	370
P3	120	420	170	570

\* 1 mbar = 100 Pa = 100 mm H<sub>2</sub>O



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AS/NZS 1716:2012 – Respiratory Protective Devices, Section 4 – Particulate Filter Respirators

Requirement	Result in % Per TGA 10 December 2020 Evidence requirements for face masks that are medical devices		Compliance / Non-Compliance
<b>4.3.5 Test of filtering efficiency</b>			
When sealed to a suitable former, and tested in accordance with Appendix I, non-powered respirator filters shall not show penetration in excess of the following:			
(a) Class P2.....not more than 6%	Specimen No.1	2.02	Compliance
	Specimen No.2	2.33	Compliance
	Specimen No.3	1.99	Compliance
	Specimen No.4	1.68	Compliance
	Specimen No.5	2.11	Compliance
	Specimen No.6	2.05	Compliance
	Specimen No.7	1.44	Compliance
	Specimen No.8	1.63	Compliance
	Specimen No.9	1.90	Compliance
	Specimen No.10	1.87	Compliance
When a single filter of a twin filter respirator is tested separately, the air flow specified for this test shall be halved. If it is possible that the single filter may be used in a single filter respirator, then the full airflow shall be used.	Single filter		N/A

Requirement	Result	Compliance / Non-Compliance
<b>4.3.6 Filters used in series</b>		
Where a separate particulate filter is used in series with any other filter, the particulate penetration shall be tested in the combined configuration in accordance with Clause 4.3.5	-	N/A



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TBA = To Be Ascertained

Document name: Differential Pressure



R.A. Vickery



CERT #6187.01

Test Report Number: 220946

### ANNEX A

**Results:**

AS/NZS 1716:2012 – Respiratory Protective Devices, Clauses 2.2.1 and 2.2.2 (Appendix D – Total Inward Leakage of Assembled Respirators – Quantitative Sodium Chloride Test)

#### Total Inward Leakage (TIL) %

Test Subject (Person)	Facial Dimension Group (As per Appendix B)	Walk	Side to Side	Up/Down	Talk	Walk	Mean
1	A	2.25	1.62	5.22	1.25	4.58	2.98
2	A	3.91	2.09	4.01	1.88	4.06	3.18
3	A	3.74	3.85	5.31	2.11	3.51	3.70
4	A	4.22	3.11	4.87	1.37	4.69	3.65
5	A	3.68	1.49	4.02	1.67	5.87	3.35
6	A	3.55	2.88	3.50	2.22	4.30	3.29
7	A	4.29	2.54	3.03	1.64	3.05	2.91
8	A	1.89	3.81	2.16	2.55	4.11	2.90
9	A	1.25	2.69	3.44	3.20	3.78	2.87
10	A	3.72	3.89	2.27	1.43	5.66	3.39
Mean							3.22

Class P1 Filters – Requirement	Result	Compliance / Non-Compliance
Individual exercise results not to exceed 22% (as per Table 2.1)	-	N/A
Mean result of Test Subjects not to exceed 22% (as per Table 2.1)	-	N/A

Class P2 Filters – Requirement	Result	Compliance / Non-Compliance
Individual exercise results not to exceed 8% (as per Table 2.1)	Complies	Compliance
Mean result of Test Subjects not to exceed 8% (as per Table 2.1)	Complies	Compliance



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*R.A. Vickery*

