VERIDIA

Certification Pack.

Nanotech P2 Particulate Respirator.

87938

This pack contains

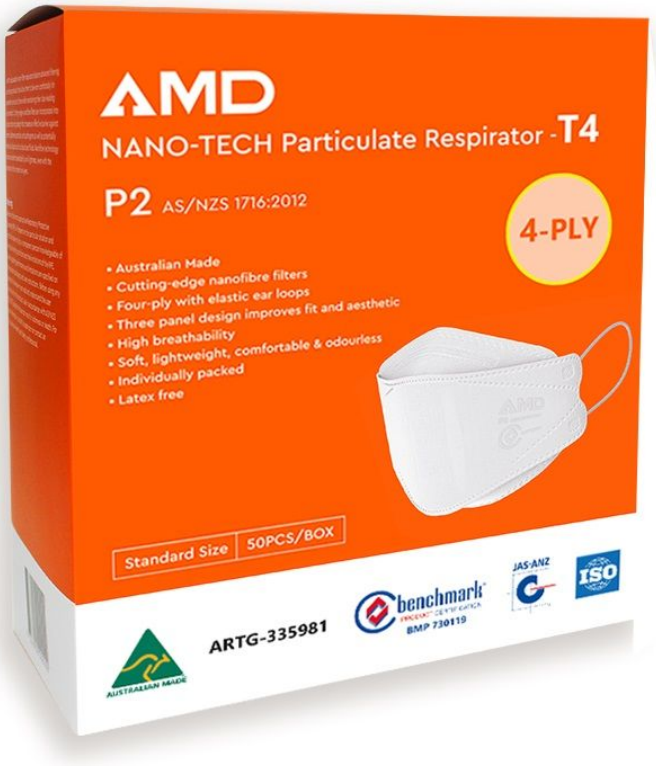
TGA Certificate

Declaration of Conformity

AS 4381:2015 Test Reports

Date Released

July 2021



Nano-Tech P2 Particulate Respirator -T4 with Ear Loop **87938**

Features	- Australian Made - Cutting-edge nanofibre filters - 4Ply with elastic ear loops - 3 panel design improves fit & aesthetic - High breathability - Soft, lightweight, comfortable & odourless - Individually packed - Latex free
Colour	- White
Unit	- Each
Pack Qty	- 25
Carton Qty	- 40 x 25

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Advanced Medical Devices (AMD) Pty Ltd

for approval to supply

Advanced Medical Devices (AMD) Pty Ltd - Public respirator, single-use

ARTG Identifier	335981
ARTG Start Date	7/05/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public respirator, single-use
Intended Purpose	A non-sterile filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates

Manufacturer Details	Address	Certificate number(s)
Advanced Medical Devices (AMD) Pty Ltd	3 / 4-8 Inglewood Place Baulkham Hills , NSW , 2153 Australia	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Advanced Medical Devices (AMD) Pty LTD
Business address:	Warehouse 3 / 4-8 Inglewood Place, Baulkham Hills, NSW, 2153, Australia
Medical device(s):	Advanced Medical Devices – P2 Surgical/medical respirator, single-use
Classification:	Class I
GMDN code and term:	57794 – Surgical/medical respirator, single-use
Scope of application:	These Declaration of Conformity procedures apply to all batches of the above product

Each kind of medical device to which the technical documentation applies, complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Standards applied:	EN1716:2012
	ISO 9001:2015

Authorised signatory:

Signature

Ed Lee, Director

Name, Position

15/June 2020

Date

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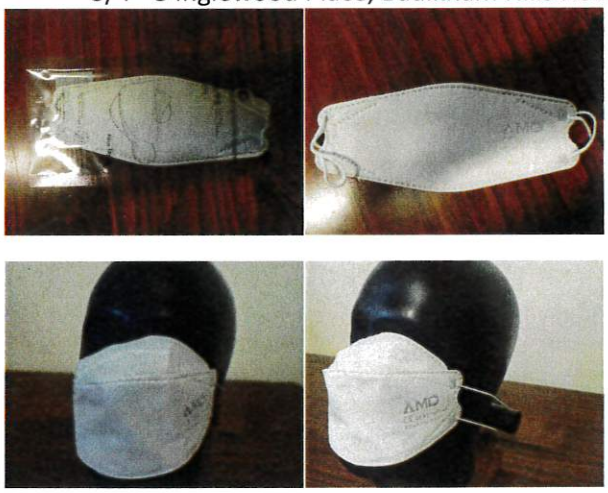
Client:	ADVANCED MEDICAL DEVICES (AMD) PTY LTD 3/4 - 8 Inglewood Place, Baulkham Hills NSW 2153 Australia
Test Report Number:	200736
Testing Requested By:	Mr Paul Roberts @ BSI Group
Client's Order Number:	Not Supplied
Date Samples Received:	3/07/2020
Date Testing Completed:	17/07/2020
Sample Description:	4 Ply Nanofilter mask, AMD NANO_TECH Particulate Respirator FFP2/P2, Twin elastic ear loops, Internal nose clip, Samples as supplied.
Manufacturer:	ADVANCED MEDICAL DEVICES (AMD) PTY LTD 3/4 - 8 Inglewood Place, Baulkham Hills NSW 2153 Australia



Testing Requested:

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

Legend:
NA = Not Applicable
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TBA = To Be Ascertained

Document name: Section 2

AUTHORISED SIGNATORY:

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Test Report Number: 200736

Sample Description: 4 Ply Nanofilter mask, AMD NANO_TECH Particulate Respirator FFP2/P2, Twin elastic ear loops, Internal nose clip, Samples as supplied.

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	To be assessed
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
4.3.3	13	Compliance
4.3.4	13	Compliance
4.3.5	14	Compliance
4.3.6	14	Compliance
Annex A – Appendix D	15	Compliance

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
2.1 General Requirements		
2.1.1 Assembled respirators		
Assembled respirators shall be made up of components which have been tested together as a system.	-	N/A
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
2.1.2 Materials		
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
2.1.3 Filters		
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.	-	
The mass of the replacement filter (or filters) shall not exceed -	-	
(a) 300g when it is to be directly connected to a half facepiece; and	-	
(b) 500g when it sis to be directly connected to a full facepiece.	-	

Requirement	Result	Compliance / Non-Compliance
2.1.4 Shelf Life		
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.	-	To be assessed

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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	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.	Complies	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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Results:

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Requirement	Result	Compliance / Non-Compliance
2.2.2 Assessment		
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
Non-powered		
- 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
Powered		
Class PAPR P1 Filters	5.0	5.0
Class PAPR P2 Filters	1.0	1.0
Class PAPR P3 Filters	0.05	0.05
Air-supplied		
Continuous flow	0.02	0.05
Positive pressure demand	0.02	0.05

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Sample Description: 4 Ply Nanofilter mask, AMD NANO_TECH Particulate Respirator FFP2/P2, Twin elastic ear loops, Internal nose clip, Samples as supplied.

Results:

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

Requirement	Result	Compliance / Non-Compliance
3.1 DESIGN REQUIREMENTS		
3.1.1 GENERAL		
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	One size fits all	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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Requirement	Result	Compliance / Non-Compliance
3.1.4 Nose Clip		
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
3.2 Performance Requirements		
3.2.1 Facial fit		
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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AS/NZS 1716:2012 – Respiratory Protective Devices, Section 3 – Facepieces Head Coverings and Harnesses

Requirement	Result	Compliance / Non-Compliance
3.2.5 Exhalation resistance – Air filtering respirators		
When tested in accordance with Appendix G at a continuous flow rate of 85 ± 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	149 Pa	Compliance

Requirement	Result	Compliance / Non-Compliance
3.2.6 Security of attachments		
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	-	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

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Results:

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

Requirement	Result	Compliance / Non-Compliance
4.1 Design and Construction		
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 To be assessed

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Results:

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

Requirement	Result	Compliance / Non-Compliance
4.2 Classification and Components		
4.2.1 Classes		
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	Compliance
(c) Class P3 – intended for use against all particulates including highly toxic materials	-	N/A

Requirement	Result	Compliance / Non-Compliance
4.2.3 Components		
The respirator shall include a particulate filter complying with Clause 4.3	Complies with Clause 4.3	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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Results:

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

Requirement	Result	Compliance / Non-Compliance
4.3.3 Simulated Wear Treatment		
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	Compliance / Non-Compliance
4.3.4 Inhalation resistance		
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	P2 at 30 ± 1 L/min = 51 Pa at 95 ± 2 L/min = 178 Pa	Non- Compliance Non- Compliance
When each filter for a twin filter respirator is tested separately, the airflow specified for a test shall be halved. If however, it is possible that the single filter may be used alone, then the full airflow shall be used. Where a particulate filter is combined with a gas filter, the inhalation maximum resistance specified for the gas filter in Clause 5.4.4 shall apply.	Single Filter Half facepiece	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_2O

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Email: viclab@bigpond.com

Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD

Test Report Number: 200736

Sample Description: 4 Ply Nanofilter mask, AMD NANO_TECH Particulate Respirator FFP2/P2, Twin elastic ear loops, Internal nose clip, Samples as supplied.

Results:

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

Requirement	Result	Compliance / Non-Compliance
4.3.5 Test of filtering efficiency		
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 P1……..not more than 20%	-	N/A
(b) Class P2……....not more than 6%	0.34%	Compliance
(c) Class P3……..…not more than 0.05%	-	N/A
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	Compliance

Requirement	Result	Compliance / Non-Compliance
4.3.6 Filters used in series		
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

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

Document name: Section 2

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Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD

Test Report Number: 200736

Sample Description: 4 Ply Nanofilter mask, AMD NANO_TECH Particulate Respirator FFP2/P2, Twin elastic ear loops, Internal nose clip, Samples as supplied.

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	6.42	7.19	6.37	7.31	3.38	6.13
2	A	7.61	3.46	3.81	6.28	4.12	5.05
3	B	6.21	4.48	3.72	4.78	4.57	4.75
4	B	6.85	6.69	4.14	4.89	6.37	5.78
5	B	6.99	6.27	3.37	5.32	7.39	5.86
6	B	7.29	5.32	4.92	5.21	6.07	5.76
7	B	4.91	6.91	5.18	6.31	5.19	5.70
8	B	4.34	6.27	5.67	3.74	4.51	4.90
9	C	5.12	3.89	4.62	5.39	4.89	4.78
10	C	4.49	4.61	4.94	5.21	7.14	5.27
Mean							5.39

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

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

Document name: Section 2

AUTHORISED SIGNATORY:

R.A. Vickery

Product testing of AMD NANO-TECH Particulate Respirator T4 FFP2/P2 Level 3 to the following test method(s) nominated by AS 4381:2015 - Bacterial filtration efficiency (EN14683:2014 Annex B)

Commercial-in-Confidence

www.csiro.au

Prepared for:	Advanced Medical Devices Pty Ltd 3 / 4-8 Inglewood Place Baulkham Hills NSW 2153
Report:	ME1064/R1
Agreement:	2020092312
Issued date:	30 September 2020

Test Report ME1064/R1
Product testing of AMD NANO-TECH Particulate Respirator T4 FFP2/P2 Level 3 to the following test method(s) nominated by AS 4381:2015 - Bacterial filtration efficiency (EN14683:2014 Annex B).

Prepared on behalf of CSIRO by

Name	Dr. Louis Kyratzis
Position	Technical Manager
Date	30 September 2020
Signature	

Authorised signatory

Name	Dr. Christopher Preston
Position	Laboratory Manager
Date	30 September 2020
Signature	

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NATA Accredited Laboratory
Accreditation No: 165
Site No: 549

Accredited for compliance with ISO/IEC 17025 – Testing.
NATA is a signatory to the ILAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of testing, medical testing, calibration and inspection reports.

Customer

Advanced Medical Devices Pty Ltd
3 / 4-8 Inglewood Place
Baulkham Hills
NSW 2153

Manufacturer

Advanced Medical Devices Pty Ltd
3 / 4-8 Inglewood Place
Baulkham Hills
NSW 2153

Test methods

1. EN14683:2014 'Medical face masks – Requirements and test methods ' Annex B - Bacterial Filtration Efficiency using CSIRO Technical Specification TS-012 v.001 (23-July-2020) - 'Test Method for Bacterial Filtration Efficiency'

Product submitted for testing

1. AMD NANO-TECH Particulate Respirator T4 FFP2/P2 Level 3

Outcome of testing

AS 4381:2015 Characteristic and Test Method	**Sample ID**	Nominated Protection Level	Requirement for nominated level of barrier protection	No. conforming results / total results	Overall Result
Bacterial filtration efficiency (BFE), % **EN 14683:2014 Annex B**	ME1064/01	Level 3	≥ 98%	5/5	Pass

Subject to the following specified limitations

As CSIRO did not undertake the sampling of the submitted items/materials from production lots/batches, nor holds information related to lot/batch size or details of the adopted sampling plan, no assessment of AQL based upon the results detailed in this report was made. It remains the responsibility of the submitting organization to determine whether these results are sufficient to establish that a suitable AQL is met under the production circumstances and the relevant sampling conditions.

Table of Contents

1. INTRODUCTION

This report details testing of submitted samples of the AMD NANO-TECH Particulate Respirator T4 FFP2/P2 Level 3 to the requirements of Bacterial filtration efficiency (EN14683:2014 Annex B) as nominated in part by Table 2 of AS 4381:2015.

2. TEST SAMPLES

2.1 Sample register

Advanced Medical Devices Pty Ltd submitted test samples as detailed in Table 1.

Table 1. Details of submitted test samples.

Sample Identification	Manufacturer	Description provided by customer/packaging	Batch/lot identification (if provided)	Number of test specimens received	Date received by CSIRO
ME1064/02	Advanced Medical Devices Pty Ltd	AMD NANO-TECH Particulate Respirator T4 FFP2/P2 Level 3	9356900000000	50	17-September-20

3. TEST SCHEDULE

The test schedule requested and applied to the samples detailed in Table 1 is provided in Table 2.

Table 2. Components of AS 4381:2015 test schedule requested by customer to be applied to test samples.

Test	Test Method	Test Schedule			
		Test method		# Samples	Sample ID
Bacterial filtration efficiency (BFE), %	EN 14683:2014, Annex B	☐	AS 4381 Level 1 of Barrier Protection (($\geq$ 95 %)		
		☐	AS 4381 Level 2 of Barrier Protection (($\geq$ 98 %)		
		☒	AS 4381 Level 3 of Barrier Protection (($\geq$ 98 %)	5	ME1064/03

3.1 Level of Barrier Protection

Australian Standard AS 4381:2015 designates three levels of barrier protection of single-use surgical masks.

3.2 Acceptable Quality Level

Where the minimum test sample numbers are adopted from ISO 22609 and EN 14683:2014, the following data is provided to assist determination of conformity based on the results in this report.

Table 3. Conformity requirements for lots achieving Acceptable Quality Levels.

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

Conformity with requirements of ISO 22609 and EN 14683:2014 (Annex C) require that an acceptable quality limit (AQL) of 4% is achieved, for example in accordance with AS 1199.1/ISO 2859-1. As CSIRO did not undertake the sampling of the submitted items/materials from production lots/batches, nor holds information related to lot/batch size or details of the adopted sampling plan, no assessment of AQL based upon the results detailed in this report was made. It remains the responsibility of the submitting organization to determine whether these results are sufficient to establish that a suitable AQL is met under the production circumstances and the relevant sampling conditions.

3.3 CSIRO Technical Specification TS-012

The test method of EN 14683 Annex B (Bacterial Filtration Efficiency) was varied as detailed in CSIRO Technical Specification TS-012 Ver 1. The specific variations are summarized as follows:

- *Staphylococcus aureus* cells were sourced frozen as commercial BIOBALLs and diluted for use in the bacterial challenge.
- The bacterial challenge was supplemented with glycerol at a concentration of 18 vol%.
- The aerosol chamber was constructed from stainless steel with bends to accommodate safe working methods.

4. TEST RESULTS

Test results in accordance with the schedule of Table 2 are provided below.

Figure 1. Images of the Advanced Medical Devices Pty Ltd (AMD) packaging and mask

4.1 Bacterial filtration efficiency (EN14683:2014 Annex B)

Table 4. Test specifications.

Test specimen dimension	100 x 100 mm
Size of the area tested	80 mm diameter
Challenge Orientation	Inside of mask faced towards bacterial challenge
Flow rate during testing	28.3 L/min

4.1.1 Test results - ME1064/01

Table 5. Test results determined in accordance with the procedure of EN14683:2014 Annex B. CFU counts from plates 3 to 6 of the impactor have been corrected through the positive hole correction method for a 400 hole impactor.

Run type/Specimen Identification		CFU Count	Test date	Bacterial Filtration Efficiency %	Estimated Measurement Uncertainty (BFE) %[1]
Positive Control 1		2257	23-September-2020		
CSIRO Specimen ID	ME1064/01-BF-1	2	23-September-2020	99.92	0.3
	ME1064/01-BF-2	2	23-September-2020	99.92	0.3
	ME1064/01-BF-3	2	23-September-2020	99.92	0.3
	ME1064/01-BF-4	2	23-September-2020	99.92	0.3
	ME1064/01-BF-5	4	23-September-2020	99.83	0.3
Positive Control 2		2492	23-September-2020		
Average Positive Control		2374			
Negative control		0	23-September-2020		

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

4.1.2 Summary - ME1064/01

Table 6. Summary of test results determined by the procedure of Appendix B of EN14683:2014.

Test fail condition is a bacterial efficiency filtration which exceeds the conditions nominated.

Test specification		Test Results		
AS 4381:2015 Level of Barrier Protection	Bacterial Filtration Efficiency, BFE			
	%	Total	Specimens Passed	Specimens Failed
Level 3	≥ 98	5	5	0
Level 2	≥ 98			
Level 1	≥ 95			

5 CONCLUSION

Based on the minimum recommended sample numbers in the referenced test methods, the summary results of testing provided in Table 7 demonstrate the submitted samples met the requirements of Bacterial Filtration Efficiency specified in Table 2 of AS 4381:2015 for the nominated level of barrier protection.

Table 7. Summary of conformity to the requirements of Table 2 of AS 4381:2015.

AS 4381:2015 Characteristic and Test Method	**Sample ID**	Nominated Protection Level	Requirement for nominated level of barrier protection	No. conforming results / total results	Overall Result
Bacterial filtration efficiency (BFE), % **EN 14683:2014 Annex B**	ME1064/02	Level 3	≥ 98%	5/5	Pass

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Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD
3/4 - 8 Inglewood Place,
Baulkham Hills NSW 2153 Australia

Test Report Number: 201079

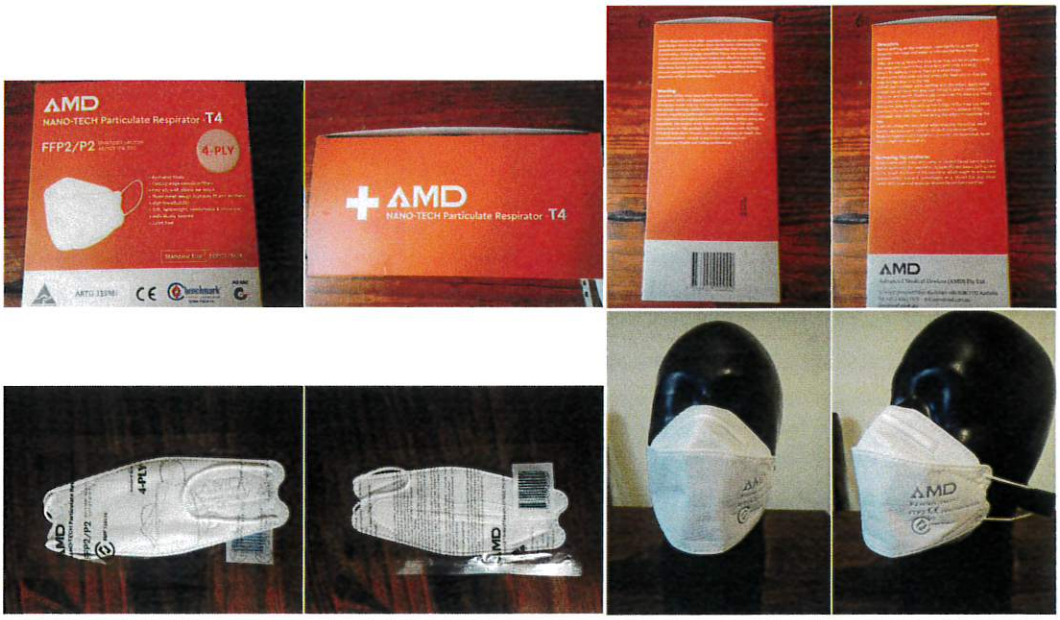
Testing Requested By: Alan Bates

Client's Order Number: Not Supplied

Date Samples Received: 26/10/2020

Date Testing Completed: 28/10/2020

Sample Description: AMD Nano-Tech Particulate Respirator – T4, FFP2/P2, Standard Size, ARTG 335981, 4 Ply, B/N: AN061020F, Expiry: 06.10.23, Australian Made, Half facepiece 4 Ply, Three Panel Design Respirator Mask, Twin elastic ear loops, Internal nose clip, Mask stamped, AMD P2 AS/NZS 1716:2012, FFP2 EN149:2001 +A1:2009, BMP 730119, Samples as supplied.



Testing Requested:

Differential Pressure (ΔP), mm H_2O/cm^2 as required by AS 4381:2015 using Test method EN 14683:2014, Annex C.

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

Document name: Differential Pressure

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Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD

Test Report Number: 201079

Sample Description: AMD Nano-Tech Particulate Respirator – T4, FFP2/P2, Standard Size, ARTG 335981, 4 Ply, B/N: AN061020F, Expiry: 06.10.23, Australian Made, Half facepiece 4 Ply, Three Panel Design Respirator Mask, Twin elastic ear loops, Internal nose clip, Mask stamped, AMD P2 AS/NZS 1716:2012, FFP2 EN149:2001 +A1:2009, BMP 730119, Samples as supplied.

Summary of Testing and Results:

Differential Pressure (ΔP), mm H_2O/cm^2 as required by AS 4381:2015 using Test method EN 14683:2014, Annex C.

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

Test sample Dimensions: 4.9 cm^2

General location of the areas of the mask specimens derived from: Centre of Mask

Flow rate used: 8 L/m

Specimen Number	Result in mm, H_2O/cm^2	Result in Pa/cm^2
1	2.37	23.26
2	2.33	22.85
3	2.37	23.26
4	2.41	23.67
5	2.33	22.85
Average Value	2.36	23.17

Samples supplied have achieved Level 1, 2 and 3 Barrier Differential pressure requirement.

Differential pressure (ΔP) requirement as per AS 4381:2015	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
	< 4.0	< 5.0	< 5.0

Legend:
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Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD
3/4 - 8 Inglewood Place,
Baulkham Hills NSW 2153 Australia

Test Report Number: 200903

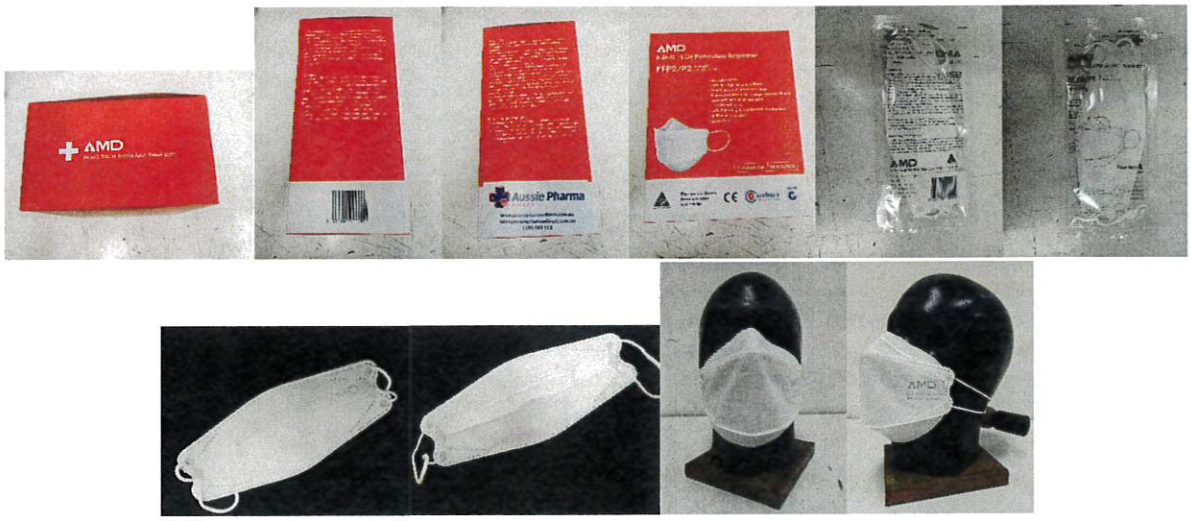
Testing Requested By: Peter Lee

Client's Order Number: Not Supplied

Date Samples Received: 2/09/2020

Date Testing Completed: 9/09/2020

Sample Description: AMD Nano-tech P2 Particulate Respirator, Four layers, White covered plastic nose clip, Twin elastic ear loops, Packaged individually. Mask marked: AND, FFP2 EN 149:2001, P2 AS/NZS 1716:2012, Manufacture date: Not Supplied, Expiry Date: Not Supplied, Manufacturer: Advanced Medical Devices Pty Ltd, Lot No: Not Supplied, Box marked: Therapeutic Goods Administration TGA-335981, Benchmark Product Certification: JAS-ANZ, Standard Size 50 PCS/Box, Samples 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

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Client: ADVANCED MEDICAL DEVICES (AMD) PTY LTD

Test Report Number: 200903

Sample Description: AMD Nano-tech P2 Particulate Respirator, Four layers, White covered plastic nose clip, Twin elastic ear loops, Packaged individually. Mask marked: AND, FFP2 EN 149:2001, P2 AS/NZS 1716:2012, Manufacture date: Not Supplied, Expiry Date: Not Supplied, Manufacturer: Advanced Medical Devices Pty Ltd, Lot No: Not Supplied, Box marked: Therapeutic Goods Administration TGA-335981, Benchmark Product Certification: JAS-ANZ, Standard Size 50 PCS/Box, Samples as supplied.

Summary of Testing and Results:

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

Samples conditioned at 21 ± 5˚C and 85 ± 10% relative humidity for a minimum of 4 hours prior to testing.

Test pressure: 21.3 kPa

General location of the areas of the mask specimens target area: Centre of Mask

Was targeting-plate method used: Yes

Specimen Number	Synthetic Blood Penetration	Result mm Hg	Pass/Fail
1 - 32	None seen	160 mmHg	Pass

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

Samples supplied have achieved Level 1 2 3 Barrier Resistance to penetration by synthetic blood requirement.

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

Legend:
NA = Not Applicable
NT = Not Tested
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Document name: Differential Pressure

AUTHORISED SIGNATORY:

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