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)

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Prepared for:	Advanced Medical Devices Pty Ltd 3 / 4-8 Inglewood Place Baulkham Hills NSW 2153
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Test Report ME1064/R1
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Prepared on behalf of CSIRO by

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Customer

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Manufacturer

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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.

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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