

Declaration of Conformity

Mun (Australia) Pty Ltd here by declares under our sole responsibility that the medical device described hereafter, *PrimeOn® Artemis Level 2 Surgical and Procedure Face Masks - White* (Product Codes: FPM21UN) has been subjected to an independent testing under the following test standards:

- **ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres,**
- **ASTM F1862 / ISO 22609 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity),**
- **ASTM F2101 Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus,** and
- **EN 14683: 2014 (Annex C) Method for Determination of Breathability (differential pressure)**

The test results are as follows:

ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	102	12131	99.16
2	76	12649	99.40
3	95	12464	99.24
4	78	12137	99.36
5	64	12354	99.48

* Test Reference: 526248

ASTM F2101 Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus, and EN 14683: 2014 (Annex C) Method for Determination Of Breathability (differential pressure)

Unit Number	Delta P (mm H ₂ O/cm ²)	Percent BFE (%)
1	2.5	99.9
2	2.4	>99.9 ^a
3	2.7	99.9
4	2.4	99.9
5	2.3	>99.9 ^a

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

* Test Reference: 526247

ASTM F1862 / ISO 22609 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

Test Pressure: 120 mm Hg

Test Article Number	Synthetic Blood Penetration	Test Article Number	Synthetic Blood Penetration
1	None Seen	17	None Seen
2	None Seen	18	None Seen
3	None Seen	19	None Seen
4	None Seen	20	None Seen
5	None Seen	21	None Seen
6	None Seen	22	Yes
7	None Seen	23	None Seen
8	None Seen	24	None Seen
9	None Seen	25	None Seen
10	None Seen	26	None Seen
11	None Seen	27	None Seen
12	None Seen	28	None Seen
13	None Seen	29	None Seen
14	None Seen	30	None Seen
15	None Seen	31	None Seen
16	None Seen	32	None Seen

* Test Reference: 784406

The above test results for standards **ASTM F2101**, **EN 14683: 2014 (Annex C)** and **ASTM F1862 / ISO 22609** qualify the product for a **Level 2** rating under the **AS4381:2015 Single-Use Face Masks for Use in Health Care** standard.

All supporting documentations including test results are retained at the Head Office, information will be provided upon request.

Regards,

Maisie Liu
 Contract & Compliance Manager
 Date: 15th May 2020