

Product Support Information

ITEMS: AssureMask Balance™ Series Procedure Earloop Face Masks
 Date of issuance: 13-May-2021

To Whom It May Concern:

This statement is issued to confirm that *AssureMask Balance™ Procedure Earloop Face Masks* have undergone testing by a qualified third-party laboratory and comply to ASTM F2100 requirements corresponding to their claimed level of protection.

Table 1. AssureMask Balance™ Level 1 – 205414, 205415, 205416 and 205417

Tests	Method	Test Result
Bacterial Filtration Efficiency (%), BFE	ASTM F2101	≥ 95
Differential Pressure (mm H ₂ O/cm ²), ΔP	EN 14683	< 5.0
Particulate Filtration Efficiency@ 0.1 micron (%), PFE	ASTM F2299	≥ 95
Synthetic Blood Penetration Resistance	ASTM F1862	Resistant @ 80mmHg
Flammability (Class 1)	16 CFR Part 1610	Pass

Item 205414, 205415, 205416 and 205417 meet ASTM F2100 Level 1 barrier protection requirements.

Table 2. AssureMask Balance™ Level 2 – 205514, 205515, 205516 and 205517

Tests	Method	Test Result
Bacterial Filtration Efficiency (%), BFE	ASTM F2101	≥ 98
Differential Pressure (mm H ₂ O/cm ²), ΔP	EN 14683	< 6.0
Particulate Filtration Efficiency@ 0.1 micron (%), PFE	ASTM F2299	≥ 98
Synthetic Blood Penetration Resistance	ASTM F1862	Resistant @ 120mmHg
Flammability (Class 1)	16 CFR Part 1610	Pass

Item 205514, 205515, 205516 and 205517 meet ASTM F2100 Level 2 barrier protection requirements.

Table 3. AssureMask Balance™ Level 3 – 205614, 205615, 205616 and 205617

Tests	Method	Test Result
Bacterial Filtration Efficiency (%), BFE	ASTM F2101	≥ 98
Differential Pressure (mm H ₂ O/cm ²), ΔP	EN 14683	< 6.0
Particulate Filtration Efficiency@ 0.1 micron (%), PFE	ASTM F2299	≥ 98
Synthetic Blood Penetration Resistance	ASTM F1862	Resistant @ 160mmHg
Flammability (Class 1)	16 CFR Part 1610	Pass

Item 205614, 205615, 205616 and 205617 meet ASTM F2100 Level 3 barrier protection requirements.

Issued by:



*Electronically signed by: Ke Xing
Reason: I authored this document
Date: May 13, 2021 21:21 EDT*

Ke Xing
Product Design Specialist, Product Development, AMD Medicom Inc.