

TECHNICAL DATA SHEET

Earloop Face Mask: ASTM F2100 Level 3 Barrier Protection

Intended Use

Procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer. Latex free.

ASTM F2100 – Level 3 Barrier Protection		
Characteristic	Testing Methodology	Acceptable Limits
Bacterial Filtration Efficiency (BFE)	ASTM F2101	BFE @ 3.0 µm large Bacteria ≥ 98%
Differential Pressure (ΔP)	EN 14683	ΔP < 6.0 mm of H ₂ O/cm ²
Particulate Filtration Efficiency (PFE)	ASTM F2299	PFE @ 0.1 µm large Latex particles ≥ 98%
Fluid Resistance	ASTM F1862	Resistant @ 160mmHg
Textile Flammability	16 CFR 1610	Class I flame spread

Characteristic		Specification	
Material Composition	Mask Body	Outer Material	Spunbond Polypropylene (SBPP)
		Filter Layer	Melt Blown Polypropylene (MBPP)
		Inner Material	Spunbond Polypropylene (SBPP)
	Nosepiece	Plastic covered steel	
	Earloop	Polyester-Spandex or Polypropylene (PP)-Spandex	
	Binding Strip	Spunbond Polypropylene (SBPP)	
Description	Rectangular face masks with shingle pleats, a shapable nosepiece and two earloops present, on each side, in order to hold mask in place.		
Appearance	Main body of mask : Presence of sealed edges. White Earloops. Logo: fully printed or embossed.		
Color	Blue		
Dimension	Body Size	Length	176 mm
		Width	90.5 mm
	Height of Earloop	66 mm	
	Pleat Depth	13 mm	
	Length of Nosepiece	120 mm	



Additional Information

Storage Condition	Country of Origin
Store under cool, clean, and dry conditions. Avoid excessive heat (over 40°C or 104°F).	Canada

Appendix 1 List of Item Codes and Attributes

Appendix 1 (List of items)

AMD Medicom Inc.

Item Code	Description	Packaging Information	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
202415	Medicom SafeMask Architect Procedure Earloop Face Masks, Level 3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic Covered Steel Nosepiece, Round Knitted Earloop Regular Earloop Length	Non-Sterile	Not Marketed In USA	Medical Device Class 1