

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	$\Delta P < 6.0 \text{ mm of H}_2\text{O/cm}^2$						
Particulate Filtration Efficiency (PFE)	ASTM F2299	PFE @ 0.1 µm large Latex particules ≥ 98%						
Fluid Resistance	ASTM F1862	Resistant @ 160mmHg						
Textile Flammability	16 CFR 1610	Class I flame spread						

Characteristic	Specification					
		Outer Material	Spunbond Polypropylene (SBPP)			
Material Composition	Mask Body	Filter Layer	Melt Blown Polypropylene (MBPP)			
		Inner Material	Spunbond Polypropylene (SBPP)			
	Nosepiece	Polypropylene (PP)-covered Iron				
	Earloop	Polyester-Spandex				
Description	Shingle pleats rectangular face masks with a shapable nosepiece and two earloops present, one on each side, in order to hold mask in place.					
Color	Black					
Earloop Style	Flat-knitted					
Dimension	Dady Cina	Length	175 mm			
	Body Size	Width	95 mm			
	Length of Earloop	172,5 mm				
	Length of Nosepiece	105 mm				

Additional Information

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

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FRM 5.04B-1 Rev 05 Effective: 23-DEC-2021

Appendix 1 (List of items)

AMD Medicom Inc.

Item Code	Description	Packaging Information	Color	Specific Attribute			Marketed in Canada as
213992	Medicom Midnight Procedure Earloop Face Masks, Level 3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Black	Plastic Covered Iron Nosepiece, Flat Knitted Earloop	Non- Sterile	Not Marketed In USA	Medical Device Class 1

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