

TECHNICAL DATA SHEET

Earloop Face Mask: ASTM F 2100 Level 2 Barrier Protection

Intended Use

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

ASTM F 2100 – Level 2 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 particules ≥ 98%
Fluid Resistance	ASTM F1862	Resistant @ 120mmHg
Textile Flammability	16 CFR 1610	Class I flame spread

Characteristic	Specification		
Materials	Mask Body	Outer Material	Spunbond Polypropylene (SBPP)
		Filter Layer	Melt Blown Polypropylene (MBPP)
		Inner Material	Spunbond Polypropylene (SBPP)
	Nose-piece	Plastic Covered Iron	
	Ear Loop	Polyester and Spandex	
Description	Shingle pleats rectangular face masks with a shapeable nosepiece and two earloops present, one on each side, in order to hold mask in place. Refer to Appendix 1 for specific attributes.		
Earloop Style	Round knitted earloop or flat knitted earloop (Refer to Appendix 1 Specific Attribute).		
Color	Refer to Appendix 1.		
Dimension	Body Size	Length	175 mm (6 7/8”)
		Width	90,5 mm (3 1/2”)
	Length of Earloop	Regular	165 mm (6 1/2”)
	Pleat Depth	14 mm (5/8”)	
	Length of Nose-piece	105 mm (4 1/8”)	

Product Image



Additional Information

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

Appendix 1 List of Item Codes and Attributes

Appendix 1 (List of items)

Item Code	Description	Packaging Information	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
205515	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1