

TECHNICAL DATA SHEET

PEDIATRIC EARLOOP FACE MASK: ASTM F2100 LEVEL 1 BARRIER PROTECTION

Intended Use

Pediatric/Child's face masks are intended to be worn by the patient/child (recommended 4-12 years of age) as a protective barrier to provide respiratory protection in procedures or situations where there is a risk of microorganism, body fluid and particulate aerosol transfer. It is a single use, non-sterile disposable device that is recommended for use in healthcare settings with appropriate adult supervision. Latex free.

ASTM F2100 – Level 1 Barrier Protection		
Characteristic	Testing Methodology	Acceptable limits
Bacterial Filtration Efficiency (BFE)	ASTM F2101	BFE @ 3.0 µm large Bacteria ≥ 95%
Differential Pressure (ΔP)	EN 14683	ΔP < 5.0 mm of H ₂ O/cm ²
Particulate Filtration Efficiency (PFE)	ASTM F2299	PFE @ 0.1 µm large Latex particules ≥ 95%
Fluid Resistance	ASTM F1862	Resistant @ 80mmHg
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	Polypropylene and Spandex	
Description	Rectangular face mask with omega pleats, a form fitting nose-piece, and two knitted earloops, one on each side, which hold the mask in place.		
Color	Blue		
Earloop Style	Round-knitted		
Dimension	Body Size	Length	140 mm
		Width	85 mm
	Height of earloop	54 mm	
	Pleat Depth	13 mm	
	Length of Nosepiece	95 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
206415-A	Medicom SafeMask Architect JR Pediatric Earloop Mask, L1	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic-covered steel nosepiece, Round-knitted earloop, "MEDICOM" Printed at the bottom of the mask	Non-Sterile	Not Marketed In USA	Medical Device Class 1