

TECHNICAL DATA SHEET

Pediatric Earloop Face Mask: ASTM F2100 Level 1 Barrier Protection

Intended Use

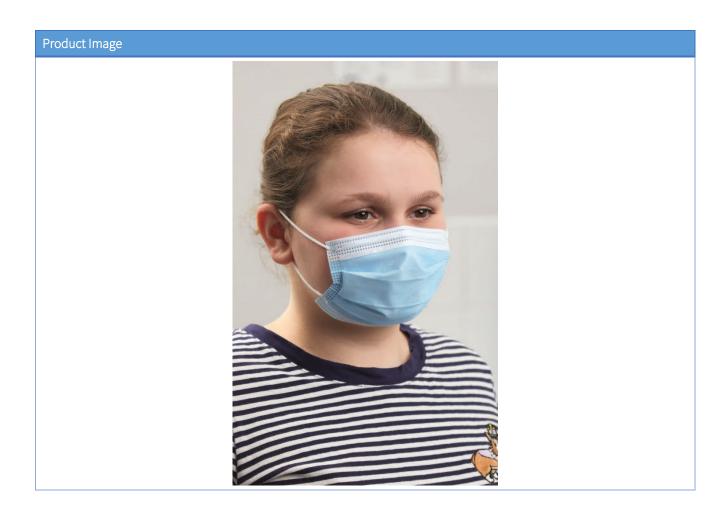
Pediatric/Child's face masks are intended to be worn by the patient/child (recommended 4-12 years of age) as a protective barrier to provide respiratory protection in procedures or situations where there is a risk of microorganism, body fluid and particulate aerosol transfer. It is a single use, non-sterile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

ASTM F 2100 – 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	$\Delta P < 5.0 \text{ mm of H}_2\text{O/cm}^2$						
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					
		Outer Material	Spunbond Polypropylene (SBPP)			
	Mask Body	Filter Layer	Meltblown Polypropylene (MBPP)			
Material Composition		Inner Material	Spunbond Polypropylene (SBPP)			
	Nosepiece	Plastic (PP) Covered Iron				
	Earloop	Polyester and Spandex				
Description	Rectangular face mask with omega pleats, a form fitting nosepiece and two flat- knitted earloops, one on each side, which hold the mask in place.					
Earloop Style	Flat-knitted					
Color	Refer to Appendix 1.					
	Pody Sizo	Length	140 mm			
Dimension	Body Size	Width	85 mm			
	Length of Earloop	130 mm				
	Pleat Depth	11 – 14 – 12 mm ± 2 mm				
	Length of Nosepiece	100 mm				

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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

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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
2035	Medicom SafeMask Junior Pediatric Earloop Masks, L1	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic-covered iron nosepiece, Flat-knitted earloop	Non-Sterile	Medical Device Class 2	Medical Device Class 1

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