

**TECHNICAL DATA SHEET**
**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 setting with appropriate adult supervision. Latex free.

ASTM F2100 – Level 1 Barrier Protection		
Characteristics	Testing Methodology	Acceptable limits
Bacterial Filtration Efficiency (BFE)	ASTM F2101-14	BFE @ 3.0 µm large Bacteria ≥ 95%
Differential Pressure (ΔP)	EN14683	ΔP < 5.0 mm of H <sub>2</sub> O/cm <sup>2</sup>
Particulate Filtration Efficiency (PFE)	ASTM F2299M-03	PFE @ 0.1 µm large Latex particules ≥ 95%
Fluid Resistance	ASTM F1862M-17	Resistant @ 80mmHg
Textile Flammability	16 CFR 1610	Class I flame spread

Characteristics	Acceptable limits		
Material Composition	Mask Body	Outer Material	Spunbond Polypropylene (SBPP)
		Filter Layer	Meltblown Polypropylene (MBPP)
		Inner Material	Spunbond Polypropylene (SBPP)
	Nose-Piece	Plastic (PP) Covered Iron	
	Earloop	Polyester and Spandex	
Description	Shingle pleats rectangular face masks with a shapeable nose-piece and two flat knitted earloops present, one on each side, in order to hold mask in place.		
Dimension	Body Size	Length	140 – 145 mm
		Width	85 – 90 mm
	Length of Earloop	130 mm	
	Pleat Depth	8 – 14 mm	
	Length of Nose-Piece	100 mm	

Visual



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)

AMD Medicom Inc.

Item Code	Description	Packaging Information	Color	Treatment
2038	Medicom SafeMask Premier Pediatric Earloop Masks, L1	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	3 Colors Polka-dot	Non-Sterile