

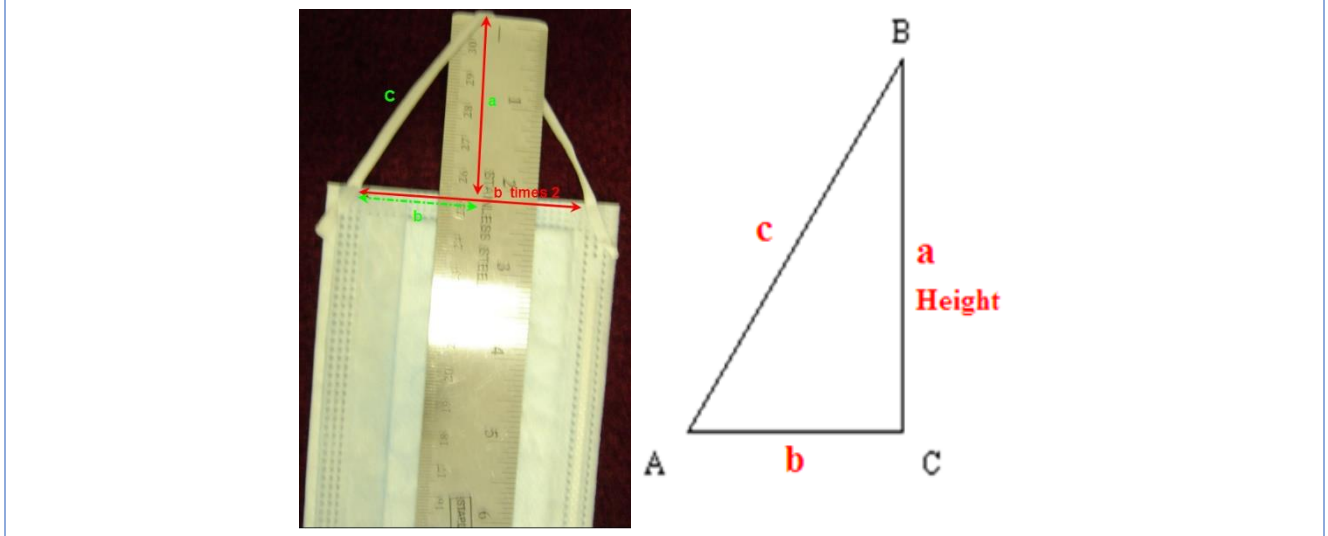
**TECHNICAL DATA SHEET**
**Earloop Face Mask: ASTM F 2100 Level 1 Barrier Protection**
**Intended Use**

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 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 <sub>2</sub> O/cm <sup>2</sup>
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	
<b>Materials</b>	Mask Body	Outer Material	Spunbond Polypropylene (SBPP)
		Filter Layer	Melt Blown Polypropylene (MBPP)
		Inner Material	Spunbond Polypropylene (SBPP)
	Nose-piece	Polypropylene (PP)-covered Iron	
	Ear Loop	Polyester and Spandex	
<b>Description</b>	Shingle pleats rectangular face masks with a shapeable nosepiece and two earloops present, one on each side, in order to hold mask in place.		
<b>Color</b>	Refer to Appendix 1		
<b>Earloop Style</b>	Flat Knitted earloop		
<b>Dimension</b>	Body Size	Length	176 mm (7")
		Width	89 mm (3 ½")
	Height of Earloop	63,5 mm (2 ½")	
	Pleat Depth	14 mm (5/8")	
	Length of Nose-piece	105 mm (4 1/8")	

## Measurement Diagram



## 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)	USA

## 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
205714	Medicom AssureMask Valiant Procedure Earloop Face Masks, L1	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	"Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205715	Medicom AssureMask Valiant Procedure Earloop Face Masks, L1	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Bright Blue	"MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205716	Medicom AssureMask Valiant Procedure Earloop Face Masks, L1	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Medium Pink	"MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205717	Medicom AssureMask Valiant Procedure Earloop Face Masks, L1	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Yellow	"MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1