

TECHNICAL DATA SHEET

Earloop Face Mask: ASTM F 2100 Level 3 Barrier Protection

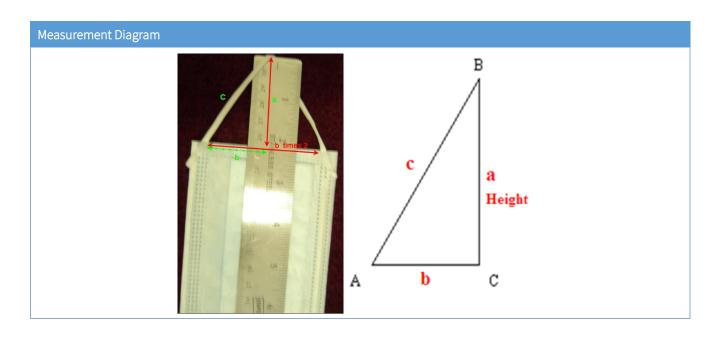
Intended Use

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

ASTM F 2100 – Level 3 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 @ 160mmHg					
Textile Flammability	16 CFR 1610	Class I flame spread					

Characteristic	Specification				
		Outer Material	Spunbond Polypropylene (SBPP)		
	Mask Body	Filter Layer	Melt Blown Polypropylene (MBPP)		
Materials		Inner Material	Spunbond Polypropylene (SBPP)		
	Nose-piece	Polypropylene (PP)-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.				
Color	Refer to Appendix 1				
Earloop Style	Flat-knitted Earloop				
	Body Size	Length	176 mm (7")		
		Width	89 mm (3 ½")		
Dimension	Height of Earloop	63,5 mm (2 ½")			
	Pleat Depth	13 mm (5/8")			
	Length of Nose-piece	120 mm (4 ¾")			







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
205914	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	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
205915	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	"Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205916	Medicom AssureMask Valiant Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	"Medicom" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1

APP1 06.03-45EN_3M Date: 10-Feb-2021 Page 1 / 1