

SafeMask® Premier

ASTM
LEVEL 1



TECHNICAL DATA SHEET



FEATURES & BENEFITS

- Non-woven spunbond outer layer provides maximum protection against fluid penetration.
- Soft, strong, ultrasonically sealed earloops attached to outside of mask prevent pulling and irritation and allow easy removal with less risk of self-contamination.
- Shingle pleat design prevents fluid pooling and cross-contamination.
- High-quality media ensures optimal filtration and breathability.
- Adjustable, enclosed nosepiece forms a strong seal to provide customized protection and comfort.

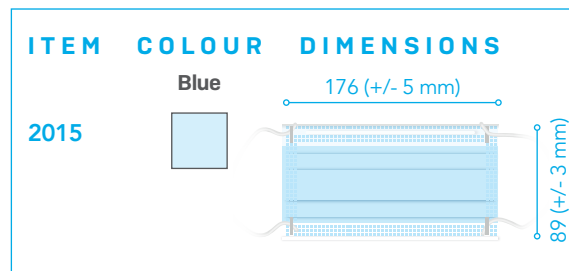
RECOMMENDED USE

- 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.

PRODUCT DETAILS

Product Name:	Medicom SafeMask® Premier Procedure Earloop Face Mask
Product Type:	Single-use, non-sterile, three-layer construction
Earloop:	Polyester and polyurethane
Nosepiece:	Aluminum
Colour:	See Appendix 1
Quantity per Inner Carton:	50
Country of Origin:	USA

DETAILED MASK DIMENSIONS	
Height of Earloop	63,5 mm
Pleat Depth	14 mm
Length of Nose-piece	120 mm



ASTM F2100 - LEVEL 1 BARRIER PROTECTION		
PERFORMANCE FACTORS	TEST METHODS	RESULT
Bacterial filtration efficiency (BFE)	ASTM F2101	≥ 95%
Sub-micron particulate efficiency at 0.1µm (PFE) /	ASTM F2299	≥ 95%
Resistant to penetration by synthetic blood	ASTM F1862	@ 80 mm Hg
Differential Pressure (ΔP)	EN 14683	< 5.0 mm H ₂ O/cm ²
Flame Spread	16 CF 1610	Class 1

NON-WOVEN SPUNBOUND OUTER & INNER LAYER

Provides maximum protection against fluid penetration. Outer and inner layers made from spunbond polypropylene (SBPP).

HIGH-QUALITY MEDIA

Ensures optimal filtration and breathability. Made from melt blown polypropylene (MBPP).

SOFT, STRONG, ULTRASONICALLY SEALED EARLOOPS

Are attached to the outside of the mask to prevent pulling and irritation and allow easy removal with less risk of self-contamination.

SOFT-BOND ULTRASONICS

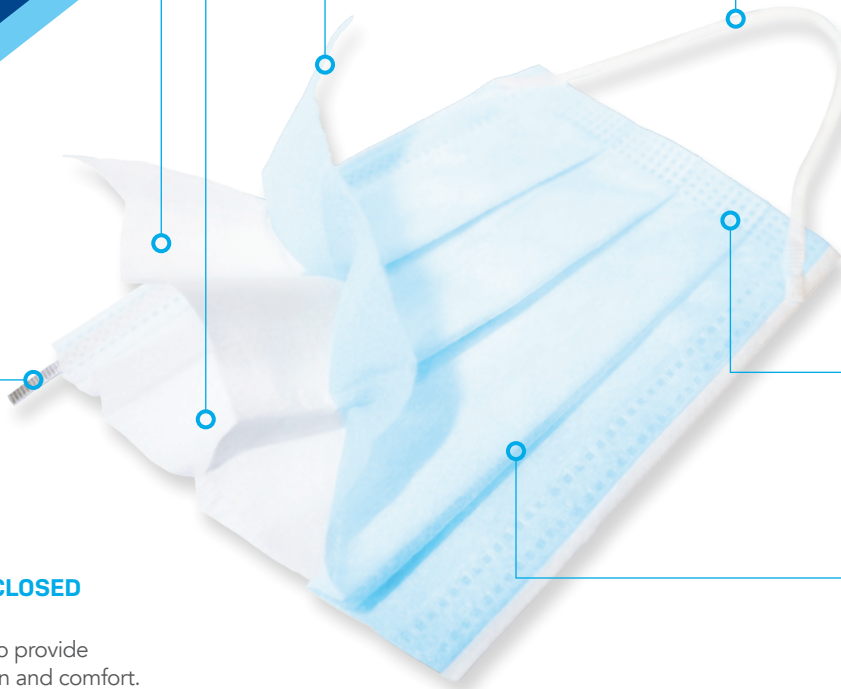
Ensure solid construction and eliminate holes and defects.

SHINGLE PLEAT DESIGN

Prevents fluid pooling and cross-contamination. Mask must be worn with pleats facing down.

ADJUSTABLE, ENCLOSED NOSEPIECE

Forms a strong seal to provide customized protection and comfort.



AVAILABLE COLOURS

Bright Blue



Yellow



White



Bright Lavender



Teal



Medium Pink



CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.
Class 1 Medical Device.
Health Canada registered medical device manufacturer.

STORAGE CONDITIONS

These masks should be disposed of after each use.
Store in a cool, dry place.
Avoid excessive heat (40 °C or 104 °F).



DONNING INSTRUCTIONS

- Fan to open pleats.
- Shape before applying to ensure a better fit.
- Pull earloops over each ear.
- With two fingers on either side of your nose, firmly shape around your nose and across your cheeks, concentrating on the bridge of your nose, to secure the seal.
- Pinch the nosepiece and make sure the base of the mask sits comfortably below your chin.

DOFFING INSTRUCTIONS

- Pull the earloops off your ears.
- Pull the mask away from your face, taking care not to touch its outer surface.
- Still holding only the earloops and taking care not to touch outer surface, dispose of mask in a clinical waste bin.
- Always wash your hands thoroughly after removing a mask.



Appendix 1 (List of items)

Item Code	Description	Packaging Information	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
2010	Medicom SafeMask Premier Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	White	Aluminum nosepiece, Polyester & Polyurethane earloop, Flat-knitted earloop; "MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2011	Medicom SafeMask Premier Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Bright Lavender	Aluminum nosepiece, Polyester & Polyurethane earloop, Flat-knitted earloop; "MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2015	Medicom SafeMask Premier Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Bright Blue	Aluminum nosepiece, Polyester & Polyurethane earloop, Flat-knitted earloop; "MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2016	Medicom SafeMask Premier Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Medium Pink	Aluminum nosepiece, Polyester & Polyurethane earloop, Flat-knitted earloop; "MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1

Appendix 1 (List of items)

Item Code	Description	Packaging Information	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
2017	Medicom SafeMask Premier Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Yellow	Aluminum nosepiece, Polyester & Polyurethane earloop, Flat-knitted earloop; "MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2018	Medicom SafeMask Premier Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/case, 500 Masks/Case	Teal	Aluminum nosepiece, Polyester & Polyurethane earloop, Flat-knitted earloop; "MEDICOM" embossed at the bottom of mask	Non-Sterile	Medical Device Class 2	Medical Device Class 1

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