

## TECHNICAL DATA SHEET

### FEATURES & BENEFITS

- o Integrated wraparound shield protects the eyes; ideal for treating high-risk patients and for procedures producing heavy amounts of airborne particles, moisture, spray and spatter.
- o Non-woven spunbond outer layer provides maximum protection against fluid penetration.
- o Soft, strong, ultrasonically sealed earloops attached to outside of mask prevent pulling and irritation and allow easy removal with less risk of self-contamination.
- o Shingle pleat design prevents fluid pooling and cross-contamination.
- o High-quality media ensures optimal filtration and breathability.
- o Adjustable, enclosed nosepiece forms a strong seal to provide customized protection and comfort.

### RECOMMENDED USE

- o 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.

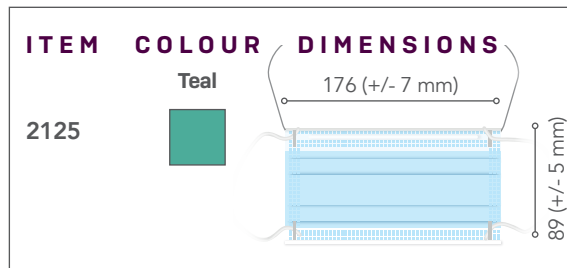
### PRODUCT DETAILS

Product Name:	<b>Ritmed ProShield™ Procedure Earloop Face Mask</b>
Product Type:	Single-use, non-sterile, three-layer construction
Ties:	Polyester and spandex
Nosepiece:	Aluminum
Visor:	Polyester film
Colour:	Teal
Quantity per Inner Carton:	25
Country of Origin:	USA



#### DETAILED MASK DIMENSIONS

Height of Earloop	64 mm
Pleat Depth	13 mm
Length of Nose-piece	120 mm
Visor Top Length	185 mm
Visor Length from Tip to Tip	300 mm
Visor Min Width	110 mm
Visor Max Width	125 mm
Visor Side Length	60 mm



#### ASTM F2100 - LEVEL 3 BARRIER PROTECTION

PERFORMANCE FACTORS	TEST METHODS	RESULT
Bacterial filtration efficiency (BFE)	ASTM F2101	≥ 98%
Sub-micron particulate efficiency at 0.1µm (PFE) /	ASTM F2299	≥ 98%
Resistant to penetration by synthetic blood	ASTM F1862	@ 160 mm Hg
Differential Pressure (ΔP)	EN 14683	< 6.0 mm H <sub>2</sub> O/cm <sup>2</sup>
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).

**INTEGRATED WRAPAROUND  
SHIELD**

Anti-fog, distortion-free eye shield ensures clear vision.

**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.

**ADJUSTABLE, ENCLOSED  
NOSEPIECE**

Forms a strong seal to provide customized protection and comfort.

**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.

**\*MASK FOR ILLUSTRATIVE  
PURPOSES ONLY**

**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**

- o Fan to open pleats.
- o Shape before applying to ensure a better fit.
- o Pull earloops over each ear.
- o 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.
- o Pinch the nosepiece and make sure the base of the mask sits comfortably below your chin.

**DOFFING INSTRUCTIONS**

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



### Appendix 1 (List of items)

Item Code	Description	Packaging Information	Color	Treatment	Marketed in USA as	Marketed in Canada as
2125	Ritmed ProShield Procedure Earloop Face Masks	25 Masks/Box, 4 Boxes/Case, 100 Masks/Case	Teal	Non-Sterile	Medical Device Class 2	Medical Device Class 1

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