

# TECHNICAL DATA SHEET



**\*MASK FOR ILLUSTRATIVE PURPOSES ONLY**

## FEATURES & BENEFITS

- o DisTech™ masks provide the reliable protection you need and the value you want.
- o These ASTM Level 2 masks are ideal for lower-risk procedures.
- o Shingle pleat design prevents fluid pooling and cross-contamination.
- o Adjustable nosepiece provides a personalized fit and quality materials ensure enhanced breathability.
- o Ultrasonically sealed, soft, stretchy, latex-free earloops ensure wearer comfort.

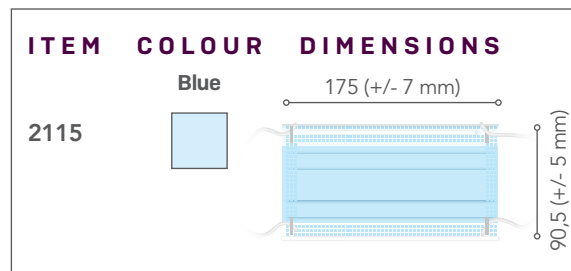
## RECOMMENDED USE

- 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 DisTech™ Procedure Earloop Face Mask</b>
Product Type:	Single-use, non-sterile, three-layer construction
Earloop:	Polyester and spandex
Nosepiece:	Plastic-covered iron
Colour:	See Appendix 1
Quantity per Inner Carton:	50
Country of Origin:	China

DETAILED MASK DIMENSIONS	
Length of Earloop	165 mm
Pleat Depth	14 mm
Length of Nose-piece	105 mm



ASTM F2100 - LEVEL 2 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	@ 120 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).

### 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.

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### AVAILABLE COLOURS

Blue



Pink



Yellow



## 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)**

<b>Item Code</b>	<b>Description</b>	<b>Packaging Information</b>	<b>Color</b>	<b>Specific Attribute</b>	<b>Treatment</b>	<b>Marketed in USA as</b>	<b>Marketed in Canada as</b>
2115	AMD-Ritmed Distech Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2116	AMD-Ritmed Distech Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2117	AMD-Ritmed Distech Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
2117-Fold	AMD-Ritmed Distech Procedure Earloop Face Masks	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case (Mask folded in half)	Yellow	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1

AMD Medicom Inc. | 2555 Chemin de l'Aviation, Montreal, Quebec, Canada H9P 2Z2