SafeMask® Architect Pro™

SURGICAL N95 RESPIRATOR

TC-84A-9375

Medicom®

TECHNICAL DATA SHEET



FEATURES & BENEFITS

- Reliable respiratory protection that filters out 95% of particulate aerosols free of oil.
- High-quality materials and duck-bill shape.
- Lightweight, breathable construction.
- Unique single split comfort band.
- Adjustable nose piece.

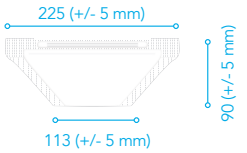
RECOMMENDED USE

- Effective against particulate aerosols free of oil; time use restrictions may apply.

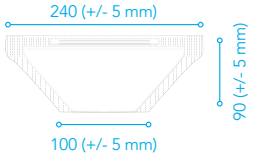
PRODUCT DETAILS

Product Name:	**Medicom SafeMask® Architect Pro™**
Product Type:	Single-use, non-sterile, three-layer construction
Strap:	Latex free synthetic rubber
Nose piece:	Plastic-covered iron
Colour:	White
Quantity per Inner Carton:	50
Country of Origin:	Canada

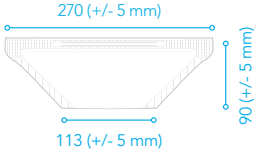
18230 (203214) — S



18232 (203314) — M



18234 (203414) — L

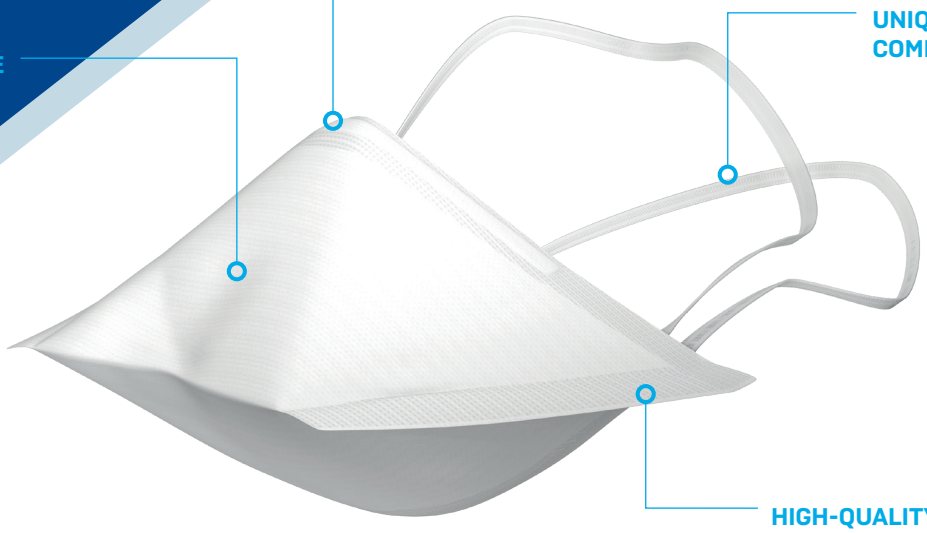


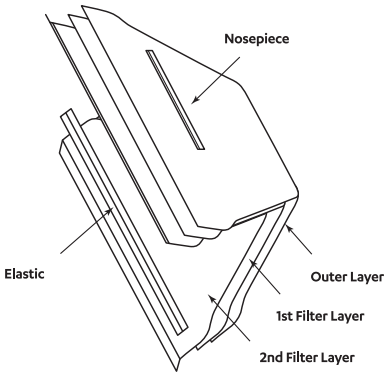
SURGICAL N95 RESPIRATOR		
TEST	**METHOD**	**RESULT**
Biocompatibility: cytotoxity, skin sensitization and skin irritation	ISO 10993-5 ISO 10993-10	Complies with the standard
Particulate filter efficiency (PFE)	42 CFR 84	≥ 95 %
Airflow resistance	42 CFR 84	Inhalation < 35 mm H_2O Exhalation < 25 mm H_2O
Fluid resistance (resistance to penetration by synthetic blood)	ASTM F1862	Level 2: 120 mm Hg
Flammability	16 CFR 1610	Class 1 - Complies
Fit	CAN/CSA Z94.4	A combination of all sizes fits> 90% of users

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For additional information and pricing,contact:
customerservice@mclgreen.com or 800.430.9555
101 Jacob Keffer Pkwy Concord, ON, Canada L4K 5N8

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CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.
Class 1 Medical Device.
Health Canada registered medical device manufacturer.
Medicom SafeMask Architect Pro N95 surgical respirator has full approval from the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) under approval number TC-84A-9375.
NIOSH certification means that the respirator has met the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).

STORAGE CONDITIONS

Store in a clean, dry location, between 5 °C and 40 °C.
Shelf life: 5 years.

2 LATEX

HANDLING AND DISPOSAL

After use, the mask may contain biohazardous fluid. Handling and disposal should be in accordance with accepted practice for biohazard waste, in compliance with applicable laws and regulations.

PRECAUTIONS

- Use only on clean, healthy skin.
- Not for use in atmospheres containing less than 19.5 % oxygen.
- Not for use in atmospheres immediately dangerous to life or health.
- Do not exceed maximum use concentrations established by regulatory standards.
- Failure to properly use and maintain this product could result in injury or death.
- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, CSA, and other applicable regulations.
- Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- Special or Critical User Instructions
  This respirator has been approved as a surgical N95 filtering facepiece respirator, for use in healthcare settings conforming to recognized standards for biocompatibility, flammability, and fluid resistance.

Proudly made in Canada.

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Appendix 1 (List of items)								
Item Code	**Description**	**Packaging Information**	**Size**	**Color**	**Specific Attribute**	**Treatment**	**Marketed in USA as**	**Marketed in Canada as**
18230 (203214)	Medicom SafeMask Architect Pro Surgical/N95 Respirator	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Small	White	Plastic-Covered Iron Nosepiece, Synthetic Rubber Elastic	Non-Sterile	NIOSH/FDA Surgical/N95, Medical Device Class 2	Medical Device Class 1
18232 (203314)	Medicom SafeMask Architect Pro Surgical/N95 Respirator	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Medium	White	Plastic-Covered Iron Nosepiece, Synthetic Rubber Elastic	Non-Sterile	NIOSH/FDA Surgical/N95, Medical Device Class 2	Medical Device Class 1
18234 (203414)	Medicom SafeMask Architect Pro Surgical/N95 Respirator	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Large	White	Plastic-Covered Iron Nosepiece, Synthetic Rubber Elastic	Non-Sterile	NIOSH/FDA Surgical/N95, Medical Device Class 2	Medical Device Class 1

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