

# Reliable respiratory protection that filters out over 95% of particulate aerosols free of oil



Made according to recognized biocompatibility, flammability and fluid resistance standards for use in healthcare facilities, the Medicom SafeMask® Architect Pro™ ensures reliable respiratory protection by filtering more than 95% of airborne particles free of oil. Its innovative "duck bill" shape provides optimal breathability with no exhalation valve required. Provides up to 8-hours of protection. Available in 3 sizes.

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).

Item codes: 203214 Small

**203314** Medium

**203414** Large

50 masks/box: 10 boxes/case





Like you, we never compromise. We use carefully selected materials and engineer our products to offer protection you can count on. We have been providing peace of mind to healthcare professionals for over 30 years. We take pride in the protection we offer, so you can take pride in yours.

For more information, please visit **medicom.com** or contact us at: cservice@medicom.ca / 1-800-361-2862

### SafeMask\* Architect Pro

SURGICAL N95 RESPIRATOR







## **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.
- o Lightweight, breathable construction.
- o 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: Synthetic rubber
Nose piece: Plastic-covered iron

Colour: White
Quantity per Inner Carton: 50
Country of Origin: Canada





113 (+/- 5 mm)

225 (+/- 5 mm)

203314 M

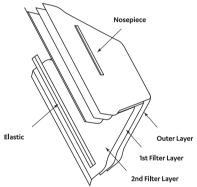
113 (+/- 5 mm)

203414

270 (+/- 5 mm)

| SURGICAL N95 RESPIRATOR  |                             |  |  |  |  |  |  |  |  |  |
|--|-----------------------------|--|--|--|--|--|--|--|--|--|
| TEST   | METHOD                      | RESULT   |  |  |  |  |  |  |  |  |
| Biocompatibility: cytotoxity, skin sensitization and skin irritation | ISO 10993-5<br>ISO 10993-10 | Complies with the standard   |  |  |  |  |  |  |  |  |
| Particulate filter efficiency (PFE)                                  | 42 CFR 84                   |  |  |  |  |  |  |  |  |  |
| Airflow resistance   | 42 CFR 84                   | Inhalation $< 35  \mathrm{mm}  \mathrm{H}_2\mathrm{O}$<br>Exhalation $< 25  \mathrm{mm}  \mathrm{H}_2\mathrm{O}$ |  |  |  |  |  |  |  |  |
| 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  |  |  |  |  |  |  |  |  |





#### **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-8375. 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.







#### 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**

- o Use only on clean, healthy skin.
- Not for use in atmospheres containing less than 19.5 % oxygen.
- o 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.





| Appendix 1 (List of items) |   |   |        |       |   |             |   |                           |  |  |  |
|----------------------------|---|---|--------|-------|---|-------------|---|---------------------------|--|--|--|
| Item Code                  | Description   | Packaging<br>Information                          | Size   | Color | Specific<br>Attribute   | Treatment   | Marketed in USA as  | Marketed in<br>Canada as  |  |  |  |
| 203214                     | Medicom SafeMask<br>Architect Pro<br>Surgical/N95<br>Respirator | 50 Masks/Box, 10<br>Boxes/Case, 500<br>Masks/Case | Small  | White | Plastic-<br>Covered<br>Iron<br>Nosepiece,<br>Synthetic<br>Rubber<br>Elastic | Non-Sterile | NIOSH/FDA<br>Surgical/N9<br>5, Medical<br>Device<br>Class 2 | Medical<br>Device Class 1 |  |  |  |
| 203314                     | Medicom SafeMask<br>Architect Pro<br>Surgical/N95<br>Respirator | 50 Masks/Box, 10<br>Boxes/Case, 500<br>Masks/Case | Medium | White | Plastic-<br>Covered<br>Iron<br>Nosepiece,<br>Synthetic<br>Rubber<br>Elastic | Non-Sterile | NIOSH/FDA<br>Surgical/N9<br>5, Medical<br>Device<br>Class 2 | Medical<br>Device Class 1 |  |  |  |
| 203414                     | Medicom SafeMask<br>Architect Pro<br>Surgical/N95<br>Respirator | 50 Masks/Box, 10<br>Boxes/Case, 500<br>Masks/Case | Large  | White | Plastic-<br>Covered<br>Iron<br>Nosepiece,<br>Synthetic<br>Rubber<br>Elastic | Non-Sterile | NIOSH/FDA<br>Surgical/N9<br>5, Medical<br>Device<br>Class 2 | Medical<br>Device Class 1 |  |  |  |

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