

## 3M™ Aura™ Health Care Particulate Respirators 1862+ and 1863+

### Description



The 3M™ Aura™ Health Care Respirators 1862+ and 1863+ are items of surgical apparel intended to be worn by health care professionals to provide respiratory protection to the wearer, help protect the wearer from splashes of potentially contaminated fluids and also to help protect both the patient and health care worker from transfer of airborne micro-organisms and particulate matter.

These products have a Bacterial Filter Efficiency  $\geq 98\%$  and are fluid resistant. The products help protect against certain particles. (see product user instructions)

Tested to EN 14683:2019 + AC:2019 “Surgical masks– Requirements and test methods” and EN 149:2001+A1:2009 “Respiratory protective devices – Filtering half masks to protect against particles –Requirements, testing, marking”.

- CE approved to the Medical Device and PPE Regulations
- Collapse resistant: suitable for work in hot, humid environments
- Sculpted nose panel helps conforms to the nose and contours of the face and helps to improve compatibility with 3M eyewear
- Innovative chin tab designed for ease of donning and adjustment to help achieve a comfortable fit
- Individual hygienic packaging protects the respirator from contamination before use
- Large, soft nose foam is comfortable on the skin
- Outer cover provides resistance to fluid splashes
- Coloured headbands for easy identification: blue for FFP2 and red for FFP3
- Respirator materials have been evaluated per ISO-10993-1 and determined to be safe for intended use
- Bacterial Filter Efficiency  $\geq 98\%$  (tested per EN14683:2019 requirements) This applies to all 3 panels of the respirator.
- Meets Fluid Resistance & ISO 22609 (as referenced in EN 14683:2019 & AS 4381:2015) for Fluid Resistance at 120mm Hg

Performance levels shared represent the minimum stated by the product performance standard. The performance results achieved by the respirator when tested often exceed the minimum stated by the standard. 3M does not base performance results upon a single product test, even if that test may be indicative of overall performance.

### Materials

The following materials are used in the production of the 3M™ Aura™ health care particulate respirators:

| Component | Material      |
|-----------|---------------|
| Straps    | Polyisoprene  |
| Staples   | Steel         |
| Nose Foam | Polyurethane  |
| Nose Clip | Aluminium     |
| Filter    | Polypropylene |

This product does not contain components made from natural rubber latex.

Maximum mass of product = 10 g

## Standards

### EN 149:2001+A1:2009

These products meet the requirements of European Standard EN 149:2001 + A1:2009, filtering facepiece respirators for use against particles. They should be used to protect the wearer from solid and non-volatile liquid particles only.

#### Designation:

NR = Non reusable (single shift use only)

D = Meets the clogging resistance requirements

### EN 14683:2019 + AC:2019

This product meets the requirements of European Standard EN 14683:2019 + AC:2019, Surgical masks – requirements and test methods. It should be used to limit the transmission of infective agents exhaled by the wearer to the environment and patients. It also provides additional protection against the penetration of bodily fluids through the product.






Products are classified by bacterial filter efficiency and fluid resistance.















#### Designation:

II = Bacterial Filter Efficiency  $\geq$  98%

R = Splash resistance pressure  $\geq$  120mm Hg

## Additional Markings

| Symbol Title                             | Symbol  |
|--|---|
| CE Mark                                  |  |
| UKCA Mark                                |  |
| Classification                           | FFPX NR D<br>(X = 1, 2 or 3)  |
| Manufacturer                             |  |
| Authorised Representative in Switzerland |  |
| Medical Device                           |  |

| Symbol Title  | Symbol  |
|---|---|
| Lot Number/ Batch Code  |    |
| Temperature Range/ Temperature Limit                            |    |
| Unique Device Identifier  |    |
| Natural Rubber Latex is not present                             |    |
| Green Dot   |    |
| Notified Body Number  | 2797  |
| Approved Body Number  | 0086  |
| Contact Address   |    |
| Authorised Representative in European Community/ European Union |    |
| Importer  |    |
| Catalogue Number  |   |
| End of Shelf Life / Use-By Date                                 |  |
| Maximum Relative Humidity/ Keep Dry                             |  |
| Caution/ Consult instructions for use                           |  |
| Do Not Re-use   |  |
| Not for individual resale                                       |  |

## Approvals

These products are CE Marked to the requirements of Community Directive 89/686/EEC or European Regulation(EU) 2016/425. The applicable legislation can be determined by reviewing the Certificate and Declaration of Conformity at <http://www.3M.com/Respiratory/certs>

These products are classified per Rule1, Annex VIII of the Medical Device Regulation (EU) 2017/745 as a Class 1 devices. (See product DoC at above link for details.)

## Applications

These respirators are suitable for use in concentrations of solid and non-volatile liquid particles up to the following limits:

| Model | EN 14683 Classification | EN149 Classification | Exhalation Valve | NPF* |
|-------|-------------------------|----------------------|------------------|------|
| 1862+ | IIR                     | FFP2 NR D            | No               | 12   |
| 1863+ | IIR                     | FFP3 NR D            | No               | 50   |

\*Many countries apply Assigned Protection Factors (APFs) which reduce the maximum concentrations of particles in which these products can be used. See national regulations and EN 529:2005. Respiratory protection is only effective if it is correctly selected, fitted and worn throughout the time when the wearer is exposed to hazards. Please contact 3M for information about which products are available outside the EU.

## Storage and Transportation

3M™ Aura™ Health Care Particulate Respirators 1862+ and 1863+ have a shelf life of 5 years. End of shelf life is marked both on the product and on the product packaging. Before initial use, always check that the product is within the stated shelf life (use by date). Product should be stored in clean, dry conditions within the temperature range: – 20°C to + 25°C with a maximum relative humidity of <80%. When storing or transporting this product use original packaging provided.

NOTE: Average conditions may exceed 25°C / 80% RH for limited periods. They can reach an average of 38°C / 85% RH, provided that this is for no more than 3 months in the shelf life of the product.

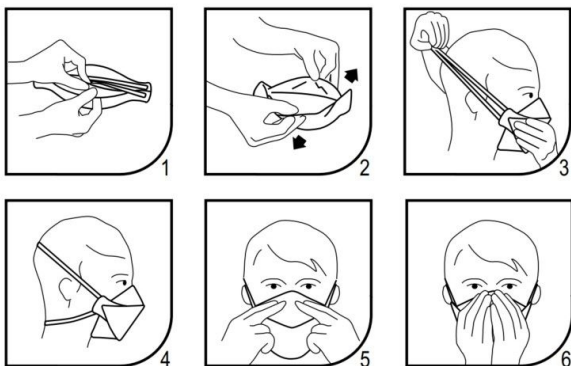
## Disposal

Contaminated products should be disposed as hazardous waste in accordance with national regulations.

## Fitting Instructions

Before fitting device, ensure hands are clean. All respirator components should be inspected for damage prior to each use.

1. With reverse side up, separate top and bottom panels to form a cup shape.
2. Ensure both panels are fully unfolded.
3. Cup respirator in one hand with open side towards face. Take both straps in other hand. Hold respirator under chin, with nosepiece up, and pull straps over head.
4. Locate the upper strap across the crown of the head and the lower strap below the ears. Straps must not be twisted. Adjust top and bottom panels for a comfortable fit, ensuring panels are not folded in.
5. Using both hands, mould nose clip to the shape of the lower part of the nose to ensure a close fit and good seal. Pinching the nose clip using only one hand may result in less effective respirator performance.



## User Seal Check

1. Cover the front of the respirator with both hands being careful not to disturb the fit of the respirator.
2. EXHALE sharply.
3. If air leaks around the nose, re-adjust the nose clip to eliminate leakage. Repeat the above seal check.
4. If air leaks at the respirator edges, work the straps back along the sides of the head to eliminate leakage. Repeat the above seal check.

If you CANNOT achieve a proper seal DO NOT enter the hazardous area. See your supervisor.

3M recommends that users are face fit tested before using a respirator and that fit testing is repeated regularly as part of their occupational protection program.

For information regarding fit testing procedures, please contact 3M.

## Warnings and Limitations

Always be sure that the complete product is:

- Suitable for the application;
  - Fitted correctly;
  - Worn during all periods of exposure;
  - Replaced when necessary.
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- Proper selection, training, use and appropriate maintenance are essential in order for the product to help protect the wearer from certain airborne contaminants.
  - Failure to follow all instructions on the use of these respiratory protection products and/or failure to properly wear the complete product during all periods of exposure may adversely affect the wearer's health, lead to severe or life threatening illness or permanent disability.
  - For suitability and proper use follow local regulations and refer to all information supplied. For more information contact a safety professional/3M representative.
  - Before use, the wearer must be trained in use of the complete product in accordance with applicable Health and Safety standards/guidance.
  - This product does not protect against gases/vapours.
  - Do not use in atmospheres containing less than 19.5% oxygen. (3M definition. Individual countries may apply their own limits on oxygen deficiency. Seek advice if in doubt).
  - Do not use for respiratory protection against atmospheric contaminants/concentrations which are unknown or immediately dangerous to life and health (IDLH).
  - Do not use with beards or other facial hair that may inhibit contact between the face and the product thus preventing a good seal.
  - This product does not eliminate the risk of contracting any disease or infection.
  - Leave the contaminated area immediately if:
    - Breathing becomes difficult
    - Dizziness or other distress occurs
    - The respirator becomes damaged
    - You taste or smell contaminants, or an irritation occurs
  - Discard and replace the respirator if it becomes contaminated with blood or other infectious material, damaged, breathing resistance becomes excessive or at the end of a shift.
  - Do not alter, modify, clean or repair this respirator.
  - In case of intended use in explosive atmospheres, contact 3M.
  - Single use only. Do not reuse.

## Important Notice

The use of the 3M product described within this document assumes that the user has previous experience of this type of product and that it will be used by a competent professional. Before any use of this product it is recommended to complete some trials to validate the performance of the product within its expected application.

All information and specification details contained within this document are inherent to this specific 3M product and would not be applied to other products or environment. Any action or usage of this product made in violation of this document is at the risk of the user.

Compliance to the information and specification relative to the 3M product contained within this document does not exempt the user from compliance with additional guidelines (safety rules, procedures). Compliance to operational requirements especially in respect to the environment and usage of tools with this product must be observed. The 3M group (which cannot verify or control those elements) would not be held responsible for the consequences of any violation of these rules which remain external to its decision and control.

Warranty conditions for 3M products are determined with the sales contract documents and with the mandatory and applicable clause, excluding any other warranty or compensation.



**Personal Safety Division**

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