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3M™ Particulate Respirators 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies

Frequently Asked Questions

We have received a number of inquiries regarding the use of 3M respirators (models number 8612F and 8670F) that have been cleared by the U.S. Food and Drug Administration (FDA) for use in public health medical emergencies. Following are some of the most commonly asked questions.

1. What is a “NIOSH N95 respirator”?

The National Institute for Occupational Safety and Health (NIOSH) primarily approves respirators to reduce exposure to airborne contaminants in occupational settings under the guidance of trained occupational safety professionals. N95 is one of nine classifications for NIOSH certified particulate respirators. The 8612F and 8670F respirators have been certified by NIOSH as an N95 for filtration efficiency. NIOSH does not evaluate respirators for use as medical devices.

2. How do the 8612F and 8670F FDA-cleared respirators differ from other N95 respirators?

The 8612F and 8670F N95 respirators are unique because they have also been cleared by the FDA for use by the public during a public health medical emergency, such as an influenza pandemic. The FDA outlined special controls for respirators used by the general public in public health medical emergencies* in order to provide reasonable assurance of their safety and effectiveness when used by the general public. As part of the clearance process established by the FDA, manufacturers must provide additional information beyond the filtration & breathability information typically required as part of the NIOSH certification process including:

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- An assessment of fit in an untrained population (how well the respirator seals to the face of the fit test panel participants)
- Testing of product components to help avoid adverse skin reactions
- Package labeling and user instructions specifically designed to communicate the information needed by consumers to understand the role of respirators in a public health medical emergency as well as how to use the respirator properly.

3M is also providing additional training materials developed for the general public on our website www.my3MN95.com.

*The complete guidance document titled “Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use By the General Public in Public Health Medical Emergencies” can be reviewed at www.fda.gov.

3. What’s the difference between these products and other FDA-cleared N95 respirators?

The 8612F and 8670F have been cleared by the FDA for use by the **general public** during public health medical emergencies. The FDA also clears other N95 respirators for use by **healthcare workers** in a surgical setting such as care of a patient who may be infected with tuberculosis. These products are often referred to as “surgical respirators” and include the appropriate statements for occupational use of the product in accordance with OSHA’s respiratory protection standard.

4. I’ve already purchased other N95 respirators for my family to use during an emergency; why shouldn’t I use them for public health medical emergencies?

Unlike the respirators you might already have, the 8612F and 8670F have been cleared by the FDA for use by the public in a public health medical emergency. The package labeling and *User Instructions* have been specifically designed to communicate the information needed to understand the role of respirators in a medical emergency as well as how to use the respirator properly in such an event. Other NIOSH-approved, N95 respirators have package labeling and user instructions designed for employers who are complying with the Occupational Safety and Health Administration’s (OSHA) regulations for respirator use. In addition, the FDA also outlined other special controls for respirators used by the general public in public health medical emergencies in order to provide reasonable assurance of their safety and effectiveness when used by the general public.

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5. What is a ‘public health medical emergency’?

In their document "Respirators for Public Health Emergencies", the FDA describes that a public health medical emergency "can range from a worldwide outbreak (pandemic) of influenza, to a biological terrorist threat such as anthrax." www.fda.gov/consumer/updates/respirators061107.html

6. How will I know when a “public health medical emergency” exists?

It is our understanding that a federal, state or local government agency will determine when a public health medical emergency exists.

7. Where can I buy a 3M respirator cleared by the FDA for use by the general public in public health medical emergencies?

FDA cleared N95 respirators specifically manufactured for use by the public will be made available through government entities, family/community preparedness organizations and safety equipment distributors. They are also available in locations such as retail pharmacies/drug stores and mass retailers, sold under 3M’s Nexcaré™ brand.

8. Should I buy these FDA cleared respirators before a public health medical emergency is declared?

You should reference the information available from the U.S. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (DHHS), World Health Organization (WHO), your state or local health department and other relevant sources as you plan your response to an emergency (please refer to website links at the end of this document). If you choose to use a respirator as part of your preparedness plan, you may want to purchase some so you can familiarize yourself with the user instructions and practice putting on the respirator before there is an emergency.

9. Have any of these respirators been cleared for use by children?

No. The FDA has only cleared the 8612F and 8670F respirators for use by adults. These respirators are not for use by children.

10. What should I do to become familiar with the respirator and how to use it?

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It's important to familiarize yourself with the respirator *User Instructions* and to practice putting on the respirator before there is a public health medical emergency. Putting the respirator on correctly means more the air you breathe goes through the respirator filter. Follow the *User Instructions* to help determine if the respirator fits you. If you are not able to get a good fit with one model respirator, try a different model. For more information on how to wear these respirators correctly, please go to the 3M website www.my3MN95.com where you will find specific training for putting on and taking off each respirator model.

11. Where can I find more information about preparing for a public health medical emergency, such as an influenza pandemic?

In addition to the information you can find on 3M's website, please visit www.pandemicflu.gov for a wide range of information and guidance on pandemic preparedness. Your state or local health department may also have information available.

12. Can these respirators be used in an occupational (work) setting?

No, the 8612F and 8670F have been cleared by the FDA for use by the general public in the event of a public health medical emergency. They are not intended for occupational use or applications.

13. Does OSHA require fit testing of these general public respirators?

OSHA does not regulate the use of respirators by the general public. In this situation the OSHA respirator program requirements do not apply. These respirators are not for occupational use or applications. 3M has developed user instructions and other training materials such as fitting posters and training videos to assist the general public user in fitting and use of the respirator. It's advisable that individuals purchasing the 8612F and 8670F respirators become familiar with these training materials.

14. Can I use these respirators for other home activities (i.e. DIY projects, etc)?

No, the 8612F and 8670F have been cleared by the FDA for public health medical emergencies only. They are not intended for any other use. The package labeling and *User Instructions* have been specifically designed to communicate to the general public the information needed to understand the role of respirators in a

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medical emergency as well as how to use the respirator properly in such an event. The package labeling and *User Instructions* for the 8612F and 8670F do not include the appropriate language for other uses, such as Do-It-Yourself projects.

15. Who is included as part of the ‘general public’?

The FDA defines the general public as consumers. This would include anyone purchasing these respirators for personal use outside of their workplace. Again, the 8612F and 8670F are not for occupational use at your place of employment.

16. If I use this respirator in a public health medical emergency, does it guarantee that I won’t get sick?

The respirator is designed to cover your nose and mouth. It can help reduce the number of airborne disease causing organisms (germs) you breathe. However, the respirator cannot eliminate the breathing in of all germs in the air and does not eliminate the possibility of contracting infection, illness, or disease. The use of a respirator will not prevent entry of germs through your skin, eyes, or other parts of your body.

17. Is use of these respirators appropriate for everyone?

- These respirators are not for use by children.
- If you have pre-existing lung disease such as asthma or emphysema, underlying heart disease such as heart failure or other health conditions, you may have difficulty breathing through respirators and should consult your healthcare provider (doctor) before use.
- Anything that comes between the respirator and your face will make the respirator less effective by interfering with its fit. Men should shave every day that they may use the respirator. Hair, jewelry and clothing should not be between your face and the respirator.

18. Can these respirators be re-used?

No. The general public respirators have been cleared by the FDA for single use only. Follow the removal and disposal steps in the *User Instructions* provide with the product. It is important to touch only the straps and not the surface of the respirator when removing due to potential contamination of the surfaces. Wash hands before and after handling the respirator.

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19. What is the difference between a NIOSH certified respirator and a surgical mask?

Respirators are designed to help reduce the wearer's exposure to airborne particles. The primary purpose of a surgical facemask is to help prevent biological particles from being expelled by the wearer into the environment. Surgical facemasks are not necessarily designed to seal to the face, therefore the potential of air leakage around the edges exists. Even those masks that appear similar to respirators have not been designed to protect the wearer from airborne hazards; therefore they should not be considered an equivalent substitute to government-approved respirators. If you are a member of the general public and wish to help reduce the number of airborne disease causing organisms (germs) you breathe you should use a NIOSH-certified respirator such as the 8612F or 8670F.

Resources:

CDC: <http://www.cdc.gov/>
DHHS: <http://www.pandemicflu.gov>
WHO: <http://www.who.int/en>

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