

Respirators from Asia Imported and Distributed by FEMA

Description

As part of 3M's efforts to fight the COVID-19 pandemic from all angles, in early April 2020, 3M reached agreement with the U.S. government on a plan that enabled FEMA to import more than 228 million respirators into the United States over a 6-month period starting in April 2020, from our plants in Asia. The U.S. Food and Drug Administration (FDA) had issued two Emergency Use Authorizations (EUAs) authorizing the use of respirators approved to other countries' standards in U.S. healthcare workplaces, per guidance from the U.S. Centers for Disease Control and Prevention (CDC) in their [Strategies for Optimizing the Supply of N95 Respirators](#). Additionally, the U.S. Occupational Safety and Health Administration (OSHA) had issued enforcement guidance allowing the [use of respirators approved to certain standards in other countries](#). It is important to note that [FDA](#) and [CDC](#) are recommending that US Healthcare facilities transition away from crisis capacity strategies such as use of non-NIOSH approved respirators, based on the increased supply of respirators. According to the CDC, "The supply and availability of NIOSH-approved respirators have increased significantly over the last several months. Healthcare facilities should not be using crisis capacity strategies at this time and should promptly resume conventional practices. Check the NIOSH Certified Equipment List to identify all NIOSH-approved respirators." **On June 30, 2021, the FDA announced the revocation of the EUAs for non-NIOSH approved respirators from China and other countries outside the US** due to multiple factors including the increase in availability of NIOSH approved respirators. This revocation is effective July 6, 2021, and affects the emergency use authorization of such respirators by healthcare personnel in healthcare settings. Visit www.fda.gov for additional information. **In addition, on July 7, 2021, OSHA rescinded their temporary enforcement discretion memorandum**, stating that "...circumstances precipitating the issuance of OSHA's respiratory protection enforcement discretion memoranda no longer exist. Therefore, where respirator supplies and services are readily available, OSHA will cease to exercise enforcement discretion for temporary noncompliance with the Respiratory Protection standard based on employers' claims of supply shortages due to the COVID-19 pandemic." Agency guidance is subject to change. Facilities should consult the latest guidance.

Questions Customers May Have

Q: Which 3M respirator models holding approvals from other countries were imported to the US and distributed by FEMA?

A: For a full list of the 3M filtering facepiece respirator models manufactured in Asia that FEMA acquired and distributing in the U.S., see this [product table](#).

Q: How will these respirators be distributed?

A: FEMA will be distributing these respirator models to state authorities, and the states will determine distribution.

Q: What approvals do they hold? What performance requirements do they meet?

A: These respirator models hold various different approvals, including, in some cases, NIOSH N95. This [product table](#) indicates which approvals are held by each model that FEMA is acquiring and distributing. See [3M Technical Bulletin - Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes](#) for additional information concerning the similarities and differences between these approvals, all of which incorporate testing for filtration efficiency and inhalation and exhalation resistance.

Q: What is a KN90 respirator?

A: KN90 respirators are respirators that meet a China government standard that requires lower filtration efficiency performance (at least 90%) than NIOSH N95 (at least 95%). The China KN90 approval is not considered similar to the U.S. NIOSH N95 approval by the U.S. CDC and U.S. OSHA. While KN90 respirators are a form of respiratory protection, the amount of exposure reduction they are designed to provide is lower than the minimum amount that U.S. OSHA and NIOSH associates with the filtering facepiece class of respirators.

Q: What should I expect if my organization receives these respirators manufactured in Asia and acquired and distributed by FEMA?

A: FEMA is shipping these respirators directly from 3M facilities in Asia and they will arrive in their Asia packaging. The model number will be printed on the packaging and the respirator. The user instructions can be found in this document: [3M Respirators in International Packaging Made Available in US during COVID-19](#).

Q: How will I find English user instructions?

A: Consistent with FDA direction, FEMA and 3M will take steps to try to ensure that English User Instructions are provided to organizations receiving these respirators, including posting User Instructions for these respirators here: [3M Respirators in International Packaging Made Available in US during COVID-19](#).

Q: How will these respirators be different/similar to respirator models usually sold in the U.S.?

A: Several of the respirator models that FEMA acquired and distributing have a construction called “vertical flatfold,” which is not usually seen in the U.S. These respirators are packaged flat, with a vertical fold through the middle, but open up into a cup shape. Like the cup-style and horizontal flatfolds that are usually sold in the U.S., these imported models have two bands and a metal noseclip. The noseclip is folded in half at the top of the facepiece. The first step in putting on these respirators is to open the facepiece into a cup shape. After that, donning (putting on) the respirator follows steps similar to those for cup-style and horizontal flat-folds. As these respirators are designed for people with facial features common in China and Asia, they may not fit as well as respirators intended for sale and use in the US. Therefore, users must be fit tested before use. If a fit test cannot be conducted, or the wearer cannot pass a fit test, then these products should be used as a facemask, not a respirator.

Some FEMA-imported respirator models are the same as models that are common in the U.S. but will be in packaging with Asian languages.

Q: Earloops are unfamiliar to me - what do I need to know?

A: In the U.S., earloops are often seen on masks but not on NIOSH-approved respirators, which typically have head bands. In some countries outside the U.S., however, it is more common for respirators to feature earloops. In countries outside the US, 3M does manufacture some certified respirators which feature earloops. Among the models imported by FEMA are several models that feature earloops. Information about which respirator models contain earloops can be found in this [product table](#). NIOSH states “limited assessment of ear loop designs indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.”

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Q: Where can I find training support?

A: User Instructions, training videos, and donning posters can be found in this [product table](#).

Q: How do I fit test these imported respirators?

A: U.S. Occupational Safety and Health Administration (OSHA) respiratory protection standards mandate that individuals using new respirator models receive training and a fit test prior to the first time they use a respirator. In addition, individuals should read and follow all user instructions, including conducting a user seal check every time they put on a respirator.

3M respirators acquired by FEMA in Asia are fit tested the same way as N95 respirators typically sold and used in the U.S. – with qualitative fit testing using Bitrex™ or saccharin, as well as quantitative fit testing using a TSI PortaCount® being acceptable. Respirator fit testing resources can be found on the [3M website](#).

Q: Will these respirators fit my workforce?

A: These respirators were designed to fit people with facial features common in China and other countries in Asia. As a result, some individuals with different facial features may not be able to achieve a satisfactory fit. U.S. customers may experience fit test passage rates that are lower than they are accustomed to. If a fit test cannot be conducted, or the wearer cannot pass a fit test, then these products should be used as a facemask, not a respirator.

Q: How do I know if a 3M respirator product that arrives in Asian language packaging is counterfeit?

A: The 3M respirators that FEMA is acquiring from 3M in Asia will be distributed by FEMA to the States, free of charge. If you receive a respirator that is one of the model numbers identified above and was distributed for free and can be traced to a FEMA source of supply, it is more likely to be an authentic 3M product. FEMA is the only entity that is acquiring significant quantities of 3M respirators directly from 3M in Asia and then importing and distributing those models of respirators in the United States. If still unsure, contact the 3M fraud hotline at 1 (800) 426-8688. We take fraudulent activity very seriously. Please report such activity immediately. For additional information, see [Fraudulent Activity, Price Gouging, and Counterfeit Products](#).

Q: What is the regulatory framework that enables this?

A: Several U.S. government agencies had issued temporary authorizations relevant to filtering facepiece respirators (FFRs) approved to other countries' standards, which authorized those respirators to be used in U.S. healthcare settings even though such use would normally not be permitted.

In early 2020 to help address respirator shortages during the Covid-19 pandemic, the U.S. Centers for Disease Control and Prevention (CDC) recommended that healthcare institutions that no longer had access to any N95 respirators consider alternative respirators that are approved by other countries for occupational use and are similar to N95 respirators as a crisis capacity strategy for optimizing the supply of N95 respirators. Similar respirators include those approved to the following standards: Australia / New Zealand P2, China KN95, Japan DS2, and Korea Special 1st Class.

On March 28, 2020, the U.S. Food and Drug Administration (FDA) issued an [EUA](#) that addresses the use of respirators approved to other countries' and region's standards during the public health emergency due to COVID-19, including those of Australia, Brazil, Europe, Japan, Korea and Mexico. On April 3, 2020, the FDA issued a second [EUA](#) that addresses respirators approved to the China standards.

The U.S. Occupational Safety and Health Administration (OSHA), the agency that [regulates the selection and use of respirators in the workplace](#), states that [only NIOSH-approved respirators may be used by U.S. workers](#). However, OSHA had issued an [Enforcement Memorandum](#) that indicated that during the COVID-19 pandemic and the resultant shortage of respiratory protection equipment, if employers have exhausted all other options to reduce exposures and explored alternative respiratory protection options, then it is preferred that respirators approved to other countries' standards be used, rather than masks or other items that are not designed to provide exposure reduction.

Several 3M filtering facepiece respirator (FFR) models were included in [Exhibit 1](#) of the March 28 EUA and [Appendix A](#) of the April 3 EUA. Key reference information for organizations that receive shipments of these respirators from FEMA can be found at: www.3m.com/airlift. Not all respirator models on these lists were imported into the United States.

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