

3M Respirators in International Packaging Made Available in US during COVID-19

On June 30, 2021, the US Food and Drug Administration (FDA) announced the revocation of the Emergency Use Authorizations (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 was effective July 6, 2021, and affects the emergency use authorization of such respirators by healthcare personnel in healthcare settings. Additional information is available on the FDA website. In addition, on July 7, 2021, The US Occupational Safety and Health Administration (OSHA), the agency that regulates selection and use of respirators in the workplace, rescinded its temporary enforcement discretion memorandum, stating that "...circumstances precipitating the issuance of OSHA's respiratory protection enforcement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.

Background

During this public health emergency of the COVID-19 pandemic outbreak, many healthcare institutions experienced shortages of N95 respirators. To help ease this situation, several United States government agencies announced temporary policies and recommendations:

- In its [Strategies for Optimizing the Supply of N95 Respirators](#), the U.S. Centers for Disease Control and Prevention (CDC) had recommended that healthcare institutions that no longer have access to NIOSH-approved N95 respirators consider respirators approved under standards used in other countries that are similar to NIOSH approved N95 filtering facepiece respirators (FFR) for occupational use.
- The U.S. Food and Drug Administration (FDA) had issued several [Emergency Use Authorizations](#) that address the emergency use of certain imported disposable FFRs that are not NIOSH-approved by healthcare personnel in the United States.
- The Occupational Safety and Health Administration (OSHA) issued an [Enforcement Memorandum](#) on April 3rd, 2020, providing interim guidance to Compliance Safety and Health Officers (CSHOs) for enforcing the Respiratory Protection standard, 29 CFR § 1910.134. Specifically, it outlines enforcement discretion to permit the use of FFRs and air-purifying elastomeric respirators "*Certified under certain standards of other countries or jurisdictions...*"

There is a possibility that NIOSH-approved FFRs generally sold in countries outside the U.S. may be made available within the U.S. While these FFRs are NIOSH approved and listed on the [Certified Equipment List](#) (CEL), they may be labeled with other certification markings and also packaged in containers that are not in English.

Individuals using respiratory protection should always carefully read and follow the *User Instructions* for the model of respirator they are using. It is very important that the user be clean-shaven and follow the donning instructions exactly to get a good seal between the respirator and the face. If you do not have a proper fit to the face, you will not get the expected protection from the respirator. Users with underlying heart or lung conditions should consult a physician prior to use. Please contact 3M and/or the appropriate local health authority with any further questions. Please ensure that everyone who receives a respirator receives appropriate User Instructions.

Below are some additional resources to help you get the proper information to the people you are serving. If you have any questions, the 3M Personal Safety Division's Technical Helpline, 1-800-243-4630, can answer questions about respirators and their use, or visit 3M.com/airlift.

Non-NIOSH Approved Respirators Emergency User Authorization (EUA) End User Information

The following 3M respirators were listed in Appendix A of the April 3rd, 2020 EUA title imported, "Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China". **Note, on June 30, 2021, the US FDA announced the revocation of the EUAs for non-NIOSH approved respirators. Visit www.fda.gov for additional information.**

- [9552/9552V, 9502, 9542, 9542V](#)
- [9501, 9501+/9501V+, 9505+, 9541, 9541V](#)
- [9001/9002](#)
- [9502+/9502V+](#)
- [8822 \(AU\), 8822 \(K\) and 8205J](#)
- [9320+ and 9322+](#)

China - KN95

User Instructions

- [3M™ Particulate Respirator 9541](#)
- [3M™ Particulate Respirator 9541V](#)
- [3M™ Particulate Respirator 9542](#)
- [3M™ Particulate Respirator 9542V](#)

- [3M™ Particulate Respirator 9505+](#)
- [3M™ Particulate Respirator 9552](#)
- [3M™ Particulate Respirator 9552V](#)
- [3M™ Particulate Respirator 9501](#)
- [3M™ Particulate Respirator 9501+](#)
- [3M™ Particulate Respirator 9501V+](#)
- [3M™ Particulate Respirator 9502](#)
- [3M™ Particulate Respirator 9502+](#)
- [3M™ Particulate Respirator 9502V+](#)

China - KN90

User Instructions

- [3M™ Particulate Respirator 9001](#)
- [3M™ Particulate Respirator 9002](#)

Korea - 1st Class

User Instructions

- [3M™ Particulate Respirator 8822](#)

Japan - DS2

User Instructions

- [3M™ Particulate Respirator 8822J/8205J - in translation](#)

Australia/New Zealand - P2

User Instructions

- [3M™ Particulate Respirator 8822](#)

European Commission - FFP2

User Instructions

- [3M™ Particulate Respirator 9320+/ 9322+](#)

NIOSH Approved Respirators

N95

User Instructions

- [3M™ Health Care Particulate Respirator and Surgical Mask 1860](#)
- [3M™ Health Care Particulate Respirator and Surgical Mask 1860S](#)
- [3M™ Particulate Respirator 8210](#)
- [3M™ VFlex™ Particulate Respirator 9105](#)
- [3M™ Particulate Respirator 9210+](#)
- [3M™ Aura™ Particulate Respirator 9211+](#)

Videos

- [Tips for using a 3M™ Vertical Flat-Fold Filtering Facepiece Respirator 9010](#)
- [Tips for using a 3M™ Flat-Fold Filtering Facepiece Respirator 9210+](#)
- [Tips for using a 3M™ Flat-Fold Filtering Facepiece Respirator 9105](#)
- [Tips for using a 3M™ Filtering Facepiece Respirator 8511](#)
- [Tips for using a 3M™ Filtering Facepiece Respirator 8210](#)
- [Tips for using a 3M™ Flat-Fold Filtering Facepiece Respirator 1870+](#)
- [Tips for using a 3M™ Filtering Facepiece Respirator 1860](#)

Videos for Reference

- [Donning and Doffing PPE for Healthcare Environments](#)
- [Tips for using vertical flat-fold FFR](#)

Documents for Reference

- [Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes](#)
- [Possible Alternatives to Surgical Filtering Facepiece Respirators: Healthcare](#)
- [Respirator Fit Testing of Employees during the COVID-19 Pandemic: United States](#)