

September 2021 Update

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Safety and Health Administration (OSHA), the agency that regulates selection and use of respirators in the workplace, rescinded its temporary enforcement discretion memorandum**, stating that “...circumstances precipitating the issuance of OSHA’s respiratory protection enforcement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.

Date: April 9, 2020

RE: U.S. Emergency Use Authorization (April 3 EUA)

Dear Valued Customer,

This letter relates to the use of the following 3M filtering facepiece respirators (FFR) that have been imported from China in response to the FFR shortage resulting from the COVID-19 outbreak: **9001/9002**.

In its Strategies for Optimizing the Supply of N95 Respirators¹, the U.S. Centers for Disease Control and Prevention (CDC) has recommended that health care 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 for occupational use.

On April 3, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (April 3 EUA)² that addresses the use by healthcare personnel in the United States of respirators manufactured and approved in China. Pursuant to the April 3 EUA, the 3M respirator models listed above are intended to be used on an emergency basis in accordance with CDC recommendations to help prevent healthcare personnel exposure to pathogenic biological airborne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak.

The 3M respirator models listed above are China KN90-approved. The classification of KN-90 differs from KN-95 in that the filter penetration allowance is 10% (rather than 5% for KN-95) and the total inward leakage test allowance is less than or equal to 11% (rather than 8% for KN-95).³ More information about these approvals and respirators – including *User Instructions* – is available at: www.3M.com/Coronavirus.

When properly selected and worn, these respirators help reduce exposure to airborne particles, including biological aerosols that may contain viruses or bacteria. The respirators listed above were designed to fit people with facial features common in China and Asia. OSHA respiratory protection standards mandate that individuals using new respirator models receive training and a fit test prior to the first time they use the respirator. In addition, individuals should read and follow all user instructions, including conducting a user seal check every time they put on a respirator.

If you experience any adverse events associated with the use of these respirators, please contact the 3M PSD Technical Service 1 (800) 243-4630.

¹[Strategies for Optimizing the Supply of N95 Respirators](#) published by U.S. Centers for Disease Control and Prevention (last accessed April 6, 2020)

²[April 3, 2020 Emergency Use Authorization](#) published by U.S. Food & Drug Administration (last accessed April 6, 2020)

³[Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes](#) published by 3M (last accessed April 6, 2020)

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