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Date: April 2020

RE: End User Letter for Non-NIOSH approved FFR Authorized for Use 8822 and 8205

Dear Valued Customer,

This letter relates to the use of the following 3M filtering facepiece respirators (FFR) that have been imported in response to the FFR shortage resulting from the COVID-19 outbreak: 8822 (AU), 8822 (K) and 8205J.

In its Strategies for Optimizing the Supply of N95 Respirators,[1] 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 March 28th, 2020, the U.S. Food and Drug Adminstration (FDA) issued an Emergency Use Authorization (March 28th EUA)[2] that addresses the use of certain imported disposable FFRs that are not NIOSH approved by healthcare personnel in the United States. Pursuant to the March 28th 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 air borne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak.

The 3M respirator models listed above are certified as meeting the requirements of either P2 as per AS/NZS 1716:2012, Special 1st as per Korea KMOEL-2017-64 or a DS2 as per Japan JMHLW-2000.[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 technical assistance helpline at 1-800-243-4630.

Sincerely,
3M Personal Safety Division

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1. See https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Frespirator-supply-strategies.html (last visited April 6, 2020).

2. See https://www.fda.gov/media/136403/download (last visited April 8, 2020).

3. Please see the 3M Technical Bulletin titled Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes for additional information concerning the similarities and differences between the China KN95 approval and the U.S. NIOSH N95 approval; available at: https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf (last visited April 8, 2020).

Personal Safety Division
3M Center, Building 235-2W-70
St. Paul, MN 55144-1000

In the United States of America
Technical Service: 1 (800) 243-4630
Customer Service: 1 (800) 328-1667
3M.com/workersafety
In Canada
Technical Service: 1 (800) 267-4414
Customer Service: 1 (800) 364-3577
3M.ca/safety