

# Decontamination of 3M Filtering Facepiece Respirators, such as N95 Respirators, in the United States - Considerations

## Description

**Decontamination is no longer recommended by the U.S. CDC as a crisis strategy. Effective June 30, 2021, the US FDA revoked the EUAs for respirator decontamination systems.**

3M does not recommend decontaminating filtering facepiece respirators (FFRs). FFRs are designed to be discarded at the end of their useful life and decontaminating FFRs may void the regulatory approval.

During this COVID-19 pandemic, certain decontamination methods had been recommended by the U.S. Centers for Disease Control and Prevention (CDC) and authorized through Emergency Use Authorizations (EUAs) by US Food and Drug Administration (FDA) as part of a reuse approach to optimize the use of available filtering facepiece respirators (FFRs). During the public health emergency, many healthcare institutions experienced shortages of FFRs such as N95 respirators. The CDC [Strategies for Optimizing the Supply of N95 Respirators](#) outline recommended conventional capacity strategies, contingency capacity strategies (during expected shortages) and crisis strategies (during known shortages). These strategies are meant to be considered and implemented sequentially. Since certain decontamination methods had been allowed by government agencies during crisis capacity, 3M collaborated with several equipment manufacturers and institutions to investigate ways for hospitals to decontaminate 3M's FFRs in line with the CDC guidance on decontamination and reuse of filtering facepiece respirators. In these studies, 3M relied upon the method developer to confirm the germicidal efficacy of the decontamination method and to provide information on potential hazards to the respirator user. 3M only evaluated the effect of the method on filtration efficiency and integrity of our respiratory protection products. Damage to the FFR from a decontamination method may result in the FFR not providing respiratory protection at the indicated level, such as N95. These results were communicated to help customers who chose to implement decontamination to do so in such a way that was less likely to damage FFRs.

**As of April 2021 the US CDC has removed decontamination or bioburden reduction as a recommended crisis strategy** stating, "Decontamination or bioburden reduction of NIOSH-approved N95 respirators is no longer a strategy to conserve supplies as the availability to NIOSH-approved respirators has significantly increased." CDC recommends that healthcare facilities promptly resume conventional practices.

The FDA also recommends US healthcare facilities transition away from decontamination or bioburden reduction. **Effective June 30, 2021, the FDA revoked the EUAs for these systems.** According to an FDA letter to [US Health Care Personnel and Facilities](#) "As of the effective date of the revocations, these devices will no longer be authorized for use by health care personnel in health care settings....Based on the increased domestic supply of respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), and consistent with CDC's updated recommendations and in alignment with the Occupational Safety and Health Administration's (OSHA) recently published Emergency Temporary Standard (ETS) to protect health care workers, the FDA believes health care facilities should not use crisis capacity strategies any longer."

For additional information, consult the resources and reference below.

## Resources and References

- FDA: [FDA In Brief: FDA Revokes Emergency Use Authorizations for Certain Respirators and Decontamination Systems as Access to N95s Increases Nationwide | FDA](#)
- FDA: [Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities | FDA](#)
- CDC: [Strategies for Optimizing the Supply of N95 Respirators: COVID-19 | CDC](#)
- OSHA: <https://www.osha.gov/coronavirus/ets>
- 3M: <https://multimedia.3m.com/mws/media/1803705O/possible-alternatives-to-surgical-filtering-facepiece-respirators-healthcare.pdf>

### 3M Company

3M Center  
St. Paul, MN 55144-1000

### Customer Questions:

1-800-537-2191

### In United States of America

Technical Service: 1-800-243-4630  
Customer Service: 1-800-328-1667  
[3M.com/workersafety](https://www.3m.com/workersafety)

### In Canada

Technical Service: 1-800-267-4414  
Customer Service: 1-800-364-3577  
[3M.ca/Safety](https://www.3m.ca/Safety)

© 3M 2021. All rights reserved.

3M is a trademark of 3M Company and its affiliates.  
Used under license in Canada. All other trademarks  
are property of their respective owners.  
Please recycle.

