Respirators for Healthcare during COVID-19: Authorized Use & Avoiding Fraudulent Products

Since December 2019, fraudulent sales of personal protective equipment (PPE) — particularly N95 and KN95 filtering facepiece respirators (FFRs) — have increased. This fact sheet provides an overview of key practices and resources to help consumers to understand approved and authorized use of respirators, to avoid purchasing fraudulent products, and to report fraud or potentially fraudulent distributors, resellers, or other suppliers.

Indicators of Fraudulent or Counterfeit Filtering Facepiece Respirators

Counterfeit FFRs are products that are falsely marketed and sold as being approved by applicable regulators (e.g., NIOSH) and conforming to the standards they claim to meet. There is little confidence in these products consistently being able to provide appropriate respiratory protection to workers. Of note, a determination of authenticity is challenging to determine by looking at a picture, but it may initially help identify if the product is possibly fraudulent. When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval, those examples and common indicators are posted here: Counterfeit Respirators / Misrepresentation of NIOSH-Approval. Some known non-compliant or counterfeit respirators are included in NPPTL Respirator Assessments to Support the COVID-19 Response International Assessment Results - Not NIOSH - Approved.

Price-Gouging

Vendors selling counterfeit FFRs may also be engaged in price gouging in violation of the anti-hoarding provision of the Defense Production Act. 50 USC 4512-13. Therefore, be wary of prices substantially different from ordinary prices; the table below of recent 3M prices may serve as a guide. As a context for price-gouging with respect to market prices for certain FFRs, 3M has not meaningfully changed the price it charges for N95 respirators as a result of the COVID-19 pandemic. The prices of single 3M N95 respirators have recently ranged from $0.68 to $3.40, depending on the model. This is one example of an approval holder authorized as NIOSH-approved. A complete list of NIOSH approval holders is available on the NIOSH Certified Equipment List. Below is a table from 3M Fraudulent Activity, Price Gouging, and Counterfeit Products.* Prices for all NIOSH approval holders are expected to be similar to those in the table below.

	3M Model Number	List Price (USD)
Surgical N95 Respirators	1804 and 1804S	$0.68
	1860 and 1860S	$1.27
	1870+	$1.78
Standard N95 Respirators	8210 and 8210 Plus	$1.02 - $1.50
	8210V	$1.48 - $1.88
	8110S	$1.08 - $1.37
	8200	$0.63 - $0.80
	8511	$2.45 - $3.11
	9105 and 9105S	$0.64 - $0.81
	9210+	$1.40 - $1.78
	9211+	$2.68 - $3.40

Indicators of Fraudulent or Counterfeit Vendors/Suppliers

The *Indicators of Fraudulent 3M Personal Protective Equipment* Liaison Information Report, prepared by the FBI and 3M, highlights the following tactics commonly used by criminals:

- Demand up-front payment of all or a substantial portion of the purchase price.
- Claim access to significant inventories of legitimate PPE, larger than appears to be reasonable in light of other available information about the vendor.
- Claim to be able to export product from a country where sources of legitimate PPE from the manufacturer are not available.
- Use legitimate brand/manufacturer names in their domain name, e-mail address, or social media page despite not having any formal corporate relationship with that brand/manufacturer.
- Circulate a manufacturer's technical data sheets, certification documents, or photos of legitimate PPE to lend authenticity.
- Use false approval numbers on counterfeit products.
- Omit certification or approval details on the external packaging or markings on PPE.

Fraudulent vendors or suppliers may also purport to be a leading manufacturer as part of a scam or may claim to be a distributor of a legitimate manufacturer. Consumers with concerns should contact the manufacturers directly for approved vendors/suppliers. For one example of a manufacturer's resource, 3M has a fraud hotline**, 800-426-8688**, and website 3M COVID-19 Anti-Fraud, Anti-Price Gouging, and Anti-Counterfeiting Reporting* for the US and Canada to help detect fraud and avoid purchasing counterfeit products, as well as the 3M Fraudulent Activity, Price Gouging, and Counterfeit Products* fact sheet.

Reporting Fraudulent Activity

If you think you have information about suspicious activity by a vendor/supplier, or believe you were a victim of a scam or attempted fraud, for any incident - including the COVID-19 response - please report it as appropriate in one or more of the following ways:

- To report PPE hoarding and price gouging, contact the **U.S. Department of Justice (DOJ)** at National Center for Disaster Fraud Hotline – **Coronavirus Response**

  Email: disaster@leo.gov
  Phone: 866-720-5721

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Complaint form: https://www.justice.gov/disaster-fraud/ncdf-disaster-complaint-form

- To report federal crimes, contact the **Federal Bureau of Investigation (FBI)** by submitting a tip online at: Electronic Tip Form

  If it involves an online sale, the complaint may be submitted to the Internet Crime Complaint Center (IC3). For a complaint related to COVID, key words should be included, such as COVID and the items in question (e.g., N95, KN95, sampling kits, swabs).

  If the complaint involves a counterfeit product, submit it to the National Intellectual Property Rights Coordination Center.

- To report problems related to medical devices or product problems, contact the **Food and Drug Administration (FDA)** through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Submit reports to the FDA through the MedWatch program in one of the following ways:

  Complete the MedWatch Online Reporting Form

  Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

- To report fraud schemes to acquire personal identifiable information, contact the **Office of the Inspector General (OIG)** COVID-19 Office of Inspector General Hotline by calling the HHS-OIG Fraud Hotline (800)-447-8477 or file a report Online.

Approved Uses of N95s and Surgical N95s

In the United States, FFRs are regulated by the Occupational Safety and Health Administration (OSHA) according to the respiratory protection standard defined in 29 CFR 1910.134. An N95 respirator is a type of FFR used in occupational settings in accordance with OSHA standards, which requires that it be approved by the National Institute for Occupational Safety and Health (NIOSH). A surgical N95 FFR is a NIOSH-approved FFR that also has been evaluated for fluid resistance, flammability, and biocompatibility in accordance with Food & Drug Administration (FDA) regulations as suitable for use during medical surgery, to protect the wearer from splashes of body fluids (e.g., blood). Surgical N95 FFRs are recommended only for use by health care personnel who need protection from both airborne hazards and jets and splashes from fluids. Standard NIOSH-approved N95s may be used in healthcare settings when enhanced fluid protection is not necessary. Any other type of NIOSH-approved respirators (e.g., elastomeric half-mask respirators [EHMRs] or powered air-purifying respirators [PAPRs]) may also be used in healthcare settings not requiring enhanced fluid-protection. Some PAPRs may also have fluid resistance claims.

Selecting and Validating Equipment

For confidence in appropriate use of a particular model of respirator in healthcare, from a particular source, purchase and use only respirators (a) included as NIOSH-approved or FDA-authorized, indicated as-such in the *Certified Equipment List* (see section below) or the emergency use authorizations (EUAs, referenced below), and not excluded; and (b) not otherwise identified as fraudulent, counterfeit, or otherwise illegitimate, per the indicators below under *International Respirator Purchases*, *Indicators of Fraudulent or Counterfeit Vendors/Suppliers*, and *Indicators of Fraudulent or Counterfeit Filtering Facepiece Respirators*.

NIOSH Respirator Information and Certified Equipment List

NIOSH provides a testing and approval program assuring respirators used in the workplace meet its standards in 42 CFR Part 84. NIOSH has Respirator Trusted-Source Information, with links to sections on NIOSH-approved respirators, including what they are, how they can be identified, and where you can get them. The second of these sections indicates means of identifying trusted sources for respiratory protection and how to find markings and NIOSH approval numbers on respirators to help verify certification. Since 1994, NIOSH has maintained a searchable, online database of NIOSH-approved respirators known as the Certified Equipment List, which can be referenced to determine which respirators are approved, and whether a particular respirator is on the list.

To find NIOSH-approved FFRs suitable for use in healthcare settings, select the "Certified Equipment List" and select the appropriate search features. Not all categories need be selected. Skipping the first box and selecting "Particulate Filtering" in the first section, "Filtering Facepiece" in the "Facepiece Type" section, and clicking on "View Results, returns potentially suitable FFRs. To restrict the list to N95s, also select "N95" under "For Protections Against." The list can be further specified by selecting a manufacturer.

If you do not find a particular product in which you are interested on the list and/or have a question about whether it is a legitimate product of the company, has been NIOSH-certified, or is suitable for the purpose, reach out to the manufacturer, not the vendor or supplier. Several manufacturers have COVID-19 hotlines set up to answer questions. Considerations for detecting fraudulent or counterfeit products are addressed in sections above.

Pandemic: FDA-Authorized Alternatives and OSHA Enforcement

During the COVID-19 pandemic, healthcare workers are often unable to get NIOSH-approved N95 FFRs because of shortages. During an emergency, the FDA may authorize use of unapproved medical products or unapproved use of approved medical products through issuing an emergency use authorization (EUA). Although NIOSH-approved respirators may ordinarily be used in routine health care, the FDA has issued EUAs for the COVID-19 pandemic for several extensions of the ordinarily approved use, as detailed below. Emergency Use Authorization provides general EUA information and a current list of all FDA-issued EUAs. Personal Protective Equipment EUAs provide specific information on EUAs addressing PPE, including N95 FFRs and other respirators, detailed further below. It includes lists of respirators authorized for use during the emergency, as well as respirators that were previously authorized, but are no longer authorized. In addition, OSHA has issued guidance for enforcement of its regulatory authority aimed at extending respirator use capabilities consistent with EUA provisions – also detailed below.

- NIOSH-Approved Air- Purifying Respirators for Use in Healthcare Settings During Response to the COVID-19 Public Health Emergency - This EUA authorizes the use of certain NIOSH-approved FFR models as alternatives to N95s for emergency use in healthcare settings by healthcare personnel, which include N99, N100, P95, P99, P100, R95, R99, R100, reusable elastomeric respirators, and PAPRs. It also authorizes use of certain types of FFRs that have been decontaminated using an authorized decontamination system or that are beyond the manufacturer's recommended shelf life (expired), if they are not damaged and if they have been held according to the manufacturer's specified storage conditions.
- OSHA Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic – This document provides guidance for enforcement discretion to permit use of FFRs "[c]ertified under certain standards of other countries or jurisdictions" according to listed specifications; or, under some circumstances, beyond the manufacturer's recommended shelf life (expired).
- Imported, Non-NIOSH-Approved Disposable Respirators – This EUA authorizes the use of imported, non-NIOSH-approved FFRs, from countries where the devices are evaluated using methods similar to NIOSH, if the

respirator model meets specified criteria. A list of authorized respirators is maintained in Exhibit 1: Authorized Respirators.

- Non-NIOSH-Approved Disposable Respirators Manufactured in China – This EUA authorizes use of imported, non-NIOSH-approved FFRs manufactured in China that meet specified criteria. A list of authorized imported, non-NIOSH-approved respirators manufactured in China is maintained in Appendix A: Authorized Respirators.
  - FDA's, "Letter to Health Care Providers on Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection," describes changes to the June 6,2020 authorization letter stating FDA will no longer be reviewing requests and adding new respirator models to Appendix A.

Frequently Asked Questions (FAQs) on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic should be consulted for additional and updated information.

NIOSH is conducting testing to assess the filtration of FFRs covered by the EUAs. Ongoing assessments and results are captured here: NPPTL Respirator Assessments to Support the COVID-19 Response International Assessment Results - Not NIOSH – Approved and Personal Protective Equipment Conformity Assessment Studies and Evaluations (PPE CASE) reports.

International Respirator Purchases

Factors to Consider When Planning to Purchase Respirators from Another Country provides information on how to avoid common pitfalls when purchasing FFRs from another country, including KN95 FFRs from China. To check whether an FFR has been evaluated by a recognized Chinese or European test laboratory, verify the notifying body and the examination certificate by checking the following resources:

- List of known International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 Accredited Test Laboratories in China* lists those capable of evaluating FFR performance.
- The European Union (EU) Commission "notified bodies" for PPE in Europe under EU Regulation 2016/425 are listed here: New Approach Notified and Designated Organizations (NANDO) Information System.* The notified body issues the EU Type-Examination Certificate to the manufacturer; this particular document should be requested and reviewed (a certificate of conformity is not an indication of full certification).
- **WARNING 1:** Even if a seller provides certificate paperwork, due diligence is still needed to ascertain validity of the paperwork. A review of documents from companies based in China has found a **significant amount of falsified documentation**. While documentation is crucial, it may not be a reliable indicator of the legitimacy of the product. Follow the steps in Factors to Consider When Planning to Purchase FFRs from Another Country.
- **WARNING 2:** Many KN95s are manufactured with ear loops instead of head straps. Many people have been unable to achieve an acceptably tight face seal for devices with ear loops and thus such devices will not provide the expected level of protection against COVID-19. KN95 respirators with ear loops are not recommended for use in healthcare settings unless they are a last resort before downgrading protection to a medical facemask or cloth face covering. Be alert to this particular aspect of design and construction when selecting and purchasing KN95s.

If a respirator is not manufactured by a NIOSH approval holder or is not listed in the aforementioned EUAs, it should not be purchased because NIOSH does not have confidence the product would perform as intended. Some known non-compliant or counterfeit respirators are included in NPPTL Respirator Assessments to Support the COVID-19 Response International Assessment Results - Not NIOSH - Approved.

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For more information

For additional information, see:

- NIOSH Respirator User Notice: "Additional Tips for Spotting Counterfeit Respirators". April 21, 2020.
- NIOSH Science Blog: "Understanding the Use of Imported Non-NIOSH-Approved Respirators". April 23, 2020.
- NIOSH Webinar – "Factors to Consider when Planning to Purchase Respirators from Another Country, Including KN95 Respirators from China", May 7, 2020.
- FDA and NIOSH's Webinar: "Importing Respirators for Health Care Personnel Use" June 23, 2020.
- NIOSH's Respiratory Protection Week 2020 webinar: "How to Spot a Counterfeit! Understanding the Misrepresentation of NIOSH Approval". September 10, 2020.

For questions or concerns regarding this Fact Sheet, contact the Healthcare Resilience Working Group at Covid.Healthcareresilience@hhs.gov.