

Coronavirus Disease 2019 (COVID-19)

Factors to Consider When Planning to Purchase Respirators from Another Country

Including KN95 Respirators from China

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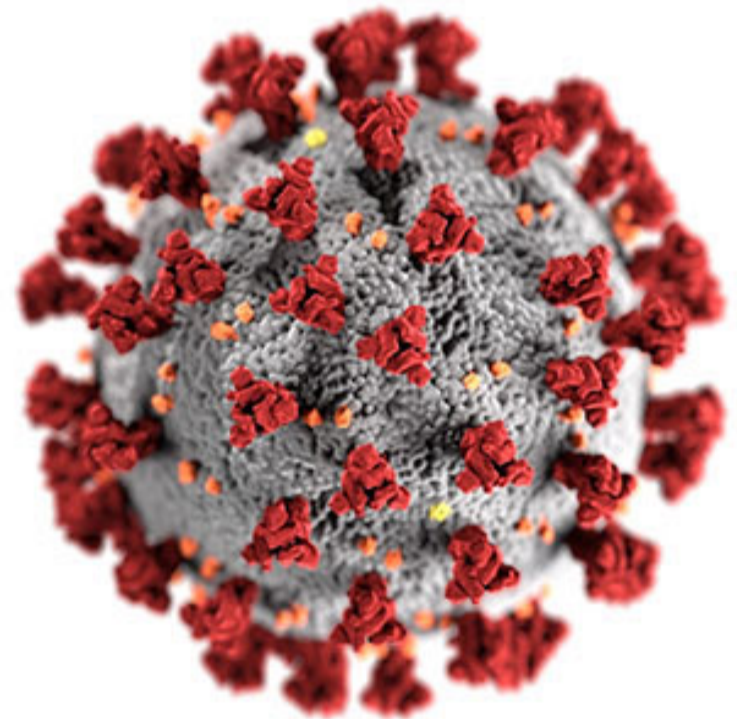
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Factors to consider when planning to purchase respirators from another country, including KN95 respirators from China

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This [webinar](#) discusses key factors to help buyers make informed procurement decisions when making a respirator purchase. The information will help to maximize the likelihood of obtaining safe and effective products that will keep workers safe.

When a respirator has been [approved by the National Institute for Occupational Safety and Health \(NIOSH\)](#), the user can be confident that the device will provide the expected level of protection, as long as it fits properly and is worn correctly. [But when there is a shortage of NIOSH-approved filtering facepiece respirators \(FFRs\)](#), as we are experiencing during the coronavirus disease 2019 (COVID-19) pandemic, other reliable options must be found. When possible, NIOSH recommends the use of **NIOSH-approved** reusable elastomeric respirators and powered air-purifying respirators (PAPRs) as alternatives to FFRs.

When a facility still needs additional FFRs, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) have [determined that other options may be appropriate to protect workers during the pandemic](#). One of these options is to purchase respirators that meet the regulatory requirements of the countries listed in the FDA's [Emergency Use Authorization](#) [EUA](#)*. However, due to the current demand, buyers should be aware that an unprecedented number of products on the market do not perform as advertised. The three most common “pitfall” scenarios include:

1. Documents are altered so FFR models appear to comply with a particular standard, but they do not.
2. Certification marks are [counterfeit](#).
3. Manufacturers' names, logos, and model numbers are counterfeit.

Key Factors




The key factors described below should assist potential purchasers of international respirators in making informed procurement and distribution decisions to keep their workers safe. Due diligence should be done to apply all factors to maximize the possibility of obtaining safe and effective products.

Potential purchasers of international respirators should evaluate the device they plan to purchase, the manufacturer, any third-party intermediary (if applicable), and the contract terms before making purchasing decisions.

Evaluation of the Device

- Considerations when purchasing any filtering facepiece respirator
 - a. The overall protection afforded by an FFR is a combination of the filter efficiency of the filtering material and the ability of the product to form a tight seal on the face of the wearer, commonly referred as the fit.
 - b. As part of an overall respiratory protection program in the workplace, OSHA requires initial fit testing in which a particular product is tested by the wearer using a recommended method.
 - c. When formal fit testing cannot be performed for each product on each person, such as when procuring an emergency supply, assessing a product's ability to fit multiple people prior to purchase is important.
 - d. Overall quality of construction should also be considered, especially if your facility is practicing the extended use of respirators.
- Evaluation of samples of the product prior to making a purchase
 - a. Obtain samples from the manufacturer.
 - b. Evaluate the respirator yourself by conducting a fit test with multiple people in your organization per the requirements of your respiratory protection program.
- Filtration efficiency
 - a. During the COVID-19 response, NIOSH is conducting modified filtration efficiency assessments of respirators not certified by NIOSH. You [can check the test results for products that have been evaluated](#) to date to see if the model(s) you are interested in are included. Note that the test results listed on the page linked above are for FFR samples submitted to NIOSH's modified test program. NIOSH does not have information on how the tested samples' performance relates to the performance of other products marked with similar model numbers.
 - i. Do NOT purchase any model that achieved filtration efficiency results <95% efficient during a NIOSH evaluation.
 - ii. For models that achieved filtration efficiency results $\geq 95\%$ efficiency during a NIOSH evaluation, continue to follow the steps below prior to purchasing the product.
 - b. [Interested parties can send a small sample size of respirators received from other countries to be tested](#) at the NIOSH National Personal Protective Technology Laboratory. This is a point-of-use assessment and is not to be used by manufacturers, distributors, suppliers, or importers attempting to sell products in the United States.
- Head harness design
 - a. Use caution when purchasing a respirator with ear loops as the head harness. Preliminary NIOSH assessments indicate it is difficult to achieve an adequate fit when wearing respirators with ear loop designs. (NIOSH-approved respirators generally do not have ear loops.)
 - b. NIOSH strongly recommends against purchasing a respirator with ear loops without conducting a fit test with multiple people (with varied facial structures) in your organization per the requirements of your respiratory protection program.






Evaluation of the Manufacturer and Seller

- Determine if the manufacturer has a test report from a laboratory that is ISO/IEC 17025 accredited and is appropriate for the performance of the model(s) you want to purchase.
 - a. NIOSH requires manufacturers to submit test data with applications for approval. For companies manufacturing respirators certified to an international standard, more rigid evaluation measures should be considered to determine whether a product conforms to standards. This should include validating that the product you intend to purchase was tested by an ISO/IEC 17025-accredited test laboratory in the country that holds the standard.
 - i. A list of known [ISO/IEC 17025-accredited test laboratories in China capable of evaluating the performance of respirators](#)   is available.
 - ii. The European Union Commission website provides a link to the list of Notified Bodies for Personal Protective Equipment in Europe – [bodies notified under Regulation \(EU\) 2016/425 on personal protective equipment](#)  (NANDO information system), many of which also have accredited test houses.
 - iii. **WARNING:** Even if you validate via the paperwork that the product has been tested by an ISO/IEC 17025-accredited test laboratory, additional due diligence is needed (see below).
 - iv. A NIOSH review of documents from companies based in China has found a significant amount of falsified documentation. While documentation is crucial, it is not a reliable indicator of the product's performance.
- Investigate the company from which you intend to purchaseⁱ
 - a. Unless you have an existing business relationship with a specific foreign manufacturer, NIOSH recommends that you conduct an appropriate review of the manufacturer prior to purchasing respirators, as outlined in the steps below. This recommendation includes companies that may have devices evaluated by NIOSH and those included in an FDA Emergency Use Authorization (EUA).
 - b. Ask colleagues about any experience they may have had with the manufacturer.
 - c. Utilize every available option to obtain more information about a manufacturer.
 - i. Obtain the manufacturer's phone number and call it.
 - ii. Ask for the company's website and review it.
 - iii. Obtain its email address. Do not trust an email from a general email provider (such as Yahoo, Gmail, @163, @126, @qq, @sina). Companies using these types of email addresses, rather than a company-specific domain, are likely not legitimate.
 - iv. Ask for the company owners' ID or passport.
 - v. Ask about the company's history in making the model(s) you are interested in purchasing, as well as how long they have manufactured respirators.
 - vi. Ask for the names and contact information for at least three U.S. purchasers of the model(s) you are thinking of purchasing that involved acquisitions of the approximate volume you are seeking.
 - vii. Ask to speak to customer support staff from the manufacturer.
 - viii. Ask if the manufacturer has a test report for the FFR model from an ISO/IEC 17025-accredited laboratory.
 - ix. Ask about the specifics of the model(s) you are interested in purchasing, including filtering media.
 - x. Ask for dated photos and videos of the model(s) you are interested in purchasing. Make sure to authenticate the photos or videos with the date. This could be done by asking the seller to write your name on a piece of paper in the photo or video as it is being taken.
 - xi. Ask for samples of the product to be shipped as quickly as possible.
 - d. Consider if you would purchase from this manufacturer in circumstances other than those existing during the COVID-19 pandemic.
- Investigate the financial strength of any third-party U.S. intermediary company you may use to make the purchase in order to confirm its ability to pay any resulting debtsⁱ.
 - a. Additional research is necessary if you are planning to use a U.S.-based, third-party intermediary company that is working with a China-based manufacturer to sell the products within the United States.
 - b. Before contracting with a third-party intermediary company to make a large purchase, have your institution's finance or accounting department review the financial statements, such as the balance sheet, of the third-party company to ascertain their financial solvency.
 - c. Ask for tax filings of the individual or company.


Evaluation of the Contract Termsⁱ

- Beware of price gouging
 - a. Under the existing circumstances surrounding the COVID-19 pandemic, KN95 models that are expected to provide N95-equivalent protection have been selling for \$2 – \$3 per unit.
 - b. If paying more than \$2 – \$3 per unit, you are likely overpaying.
 - c. Any per-unit price below \$2 – \$3 is suspect. This will change through time, as the circumstances change.
- Do not be pressured into prepaying for your purchase.
- Establish provisions in the contract to protect your purchase through any third-party U.S. intermediary company you may use to make the purchase
 - a. After conducting the necessary third-party intermediary company research, ask the third party if it is willing to take responsibility for the product, specifically the financial risk, should the product have authenticity or quality issues.
 - b. Ask the third-party U.S. intermediary if it is willing to financially guarantee the authenticity of the products.
 - c. If the third-party U.S. intermediary is willing to provide a guarantee, make sure it has the financial strength to cover the loss of the entire amount of the order.
 - d. Ask if the manufacturer is willing to agree to a three-party contract on the purchase agreement whereby the manufacturer also guarantees the authenticity of its product.

FDA Emergency Use Authorization

- [March 28 FDA EUA on NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency](#) 
- [March 28 FDA EUA on imported non-NIOSH approved FFRs](#) 
- [Exhibit 1 to FDA's March 28 EUA – list of authorized respirators](#) 
- [April 3 FDA EUA on non-NIOSH approved respirators manufactured in China](#) 
- [Appendix A to FDA's April 3 EUA](#)  – list of authorized respirators manufactured in China

Footnote

ⁱ The National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) would like to extend its gratitude to the [Indiana Economic Development Corporation](#)  for its expertise and extensive input into this document.