

HIGH PRIORITY - H0642 : COVID-19 – ECRI Exclusive Hazard Report

Use of Imported N95-Style Masks, without NIOSH Certification or Independent Lab Validation, May Put Healthcare Workers and Patients at Risk during the COVID-19 Pandemic

Medical Device Hazard Report - Published 9/22/2020

UMDNS Terms

Respirators, Air-Purifying, Particulate [20359]

Geographic Regions

Worldwide

Suggested Distribution

Infection Control, Materials Management, Risk Management/Continuous Quality Improvement

Problem

- Use of imported N95-style respirators (face-filtering respirators [FFRs]) that lack NIOSH certification may not provide the same level of wearer protection as certified models.
- Testing has shown that 60-70% of the imported non-NIOSH certified respirator alternatives currently exhibit filtration performance significantly inferior to NIOSH-certified N95s.
- Use of non-NIOSH approved respirators, especially for aerosol-generating procedures (AGPs), may increase staff and patient exposure to COVID-19.

**Need Mask & Gown Testing?**Contact priceguide@ecri.org to learn about ECRI's testing capabilities.

ECRI Recommendations

Purchasing imported non-NIOSH certified FFRs (e.g., KN95s):

- Consider using KN95s or other non-NIOSH-certified FFRs only as a last resort when treating COVID-19 patients, and only when NIOSH-certified N95s or other respirators offering comparable or better protection (e.g., N99s, N100s, PAPRs, reusable respirators) are unavailable.
- Ensure that non-NIOSH-certified FFRs have been properly tested and evaluated before use when treating suspected or positive COVID-19 patients.
 - Two characteristics in particular should be investigated:
 - Filtration efficiency—must be at least 95% to provide the equivalent protection of an N95.
 - Proper fit—to work properly, the FFR must seal tightly against the wearer's face; fit testing is critical.
 - ECRI can assist with the testing and evaluation of FFRs. Interested parties can contact priceguide@ecri.org for more information.
- Do not rely on the manufacturer's claim alone for evidence of conformance with standard filtration tests (e.g., EN149, GB2626).
 - Ask the manufacturer whether it has a test report from an ISO/IEC 17025 accredited laboratory to support filtration performance.
 - If the manufacturer has a report, request a copy for review. ECRI can assist you in interpreting the report.

- Before purchasing non-NIOSH-certified FFRs:
 - Request samples to be evaluated.
 - Recognize that ear loop retention straps are generally considered unacceptable by NIOSH for sealing the mask against the face; head/neck straps are the standard for U.S. NIOSH-certified N95s (see Figures 1 and 2 below).



Figure 1: KN95



Figure 2: KN95

- Have samples tested by an independent test lab for filtration efficiency to verify performance.
 - Manufacturer test reports or certificates are not a guarantee. From reviewing documents from companies based in China, NIOSH has determined that a significant number provide falsified documents.
 - ECRI can assist with the testing and evaluation of FFRs. Interested parties can contact priceguide@ecri.org for more information.
- Do not purchase any respirators with filtration efficiency below 95%.

- Conduct fit tests with multiple people in your facility to see whether fit will be a problem.
- If you purchase KN95 or other non-NIOSH-approved FFRs that have filtration efficiency less than 95%, consider using them for non-surgical no-splash procedures in which surgical or procedure masks are currently used.
 - The FFRs with filtration efficiency less than 95% may actually provide superior filtration protection over surgical or procedure masks because, unlike face masks, properly fitting respirators closely conform to and seal against the wearer's face, ensuring that air being breathed is filtered. For example, an FFR with 80-90% filtration efficiency will typically provide more respiratory protection than a surgical or procedure mask.

How to assess foreign FFR manufacturers:

- Determine whether other healthcare facilities have purchased from the manufacturer and what their experience was.
- Contact the company if contact information is available.
 - Ask how long the firm has been making them.
 - Ask for names and contact information for U.S. purchasers of the FFR models under consideration.
 - Ask whether the manufacturer is a NIOSH-approval holder, and confirm by checking the [NIOSH Certified Equipment List \(CEL\)](#).
 - Ask for ISO/IEC 17025 accredited laboratory test reports demonstrating the filtration efficiency for the FFR.
 - Ask for current photos of the model of interest.
 - Request samples for evaluation.

Background

- The shortage of N95 masks became evident soon after the pandemic began.
- Many overseas manufacturers sprung up to address the shortfall—The New York Times determined that more than 67,000 companies have registered with China to make or distribute masks.
- A high percentage of the Chinese companies are either start-ups or repurposed manufacturing companies (e.g., former manufacturers of automotive supplies, sports equipment, toys)

- Although U.S. domestic production capacity for N95s has significantly increased, ECRI is still hearing that there are widespread limits on quantities that can be purchased.
 - Healthcare facilities report that the U.S. government is competing for the available product to build stockpiles against future outbreaks.
- U.S. healthcare facilities are reportedly being inundated with offers for KN95 and other imported FFR masks from overseas and domestic distributors. Chinese KN95 masks are one of the most prevalent types of imported FFRs.
- Chinese regulatory filtration efficiency requirements for KN95 masks are nearly identical to NIOSH requirements for N95 FFRs, but there is no guarantee that what you buy will meet KN95 filtration requirements.
- You cannot judge the authenticity of a respirator by its appearance, labeling, or packaging.
- ECRI testing of imported FFRs has revealed that 60-70% provide only sub-95% filtration performance.
 - This trend aligns with what NIOSH has found through their own testing; as of September 2, 2020, 53% of the 358 FFR models tested did not meet N95 filtration requirements
- In some instances, ECRI has received samples of imported respirators that, despite being labeled as being the same model, look slightly different, and perform significantly differently in filtration testing.
- The KN95 masks ECRI has tested all have ear loop retention straps. NIOSH has found that 9 out of 10 are equipped with these rather than head/neck straps (see Figures 3 and 4 at right).



Figure 3: Legitimate Dasheng model DTC3X N95

- Filters >95% of airborne particles
- Headband design
- Ultrasonic welding technology



Figure 4: Counterfeit model DTC3X N95 (note the ear loop design)

References

1. [CDC: Factors to consider when planning to purchase respirators from another country](#)
2. [CDC: Counterfeit respirators/misrepresentation of NIOSH approval](#)

Comments

This alert is a living document and may be updated when ECRI receives additional information.

About ECRI

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