Use of KN95 Respirators

Updated August 28, 2020

What’s been updated: Two models of KN95 respirator produced by San Huei and distributed by ASP Global have been NIOSH-certified by an independent lab. These KN95 respirators are now approved for use and are being recommended for use settings where colleagues have not yet completed fit testing, such as our national health ministries, for example. MercyOne Senior Communities, Supplies of these specific models, in which Logistics has coordinated independent testing, are adequate to support fit testing as well as, daily use in these health ministries, and others.

Background:

KN95 respirators are manufactured in China and have been imported for use in the U.S. The FDA published an umbrella Emergency Use Authorization (EUA) that addresses all KN95 respirators that meet U.S. certification requirements as equivalent to N95 respirators from U.S. manufacturers. In June 2020, the FDA revoked the EUA for some models of KN95 respirators due to concerns regarding the filtration capacity. CDC’s National Institute for Occupational Safety and Health (NIOSH) also has conducted testing of KN95 as well as other equivalent respirators from other countries. Trinity Health sent KN95 respirators to independent testing facilities to confirm the filtration capacity. Results for these tests were received in August 2020.

KN95 respirators are required to meet the US standard for certification issued by NIOSH, i.e. published in 42 Code of Federal Regulations section 84. These respirators have assigned protection factors (APF) of at least 10 and specifics are outlined in the standards and guidance documents listed below from the CDC. The continuously updated list of these are available at:

- [https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html](https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html)

Under FDA’s umbrella EUA an Appendix A is also available and lists details on KN95s and other respirators from other countries. This appendix is available at:


Update:

MercyOne medical centers are to continue to check all donated KN95 respirators, as well as any KN95 respirators purchased locally, against the FDA list Appendix A & NIOSH web site above to confirm their EUS and testing by NIOSH meet U.S. requirements.

- If the KN95 does not appear on the above lists, the KN95 cannot be used as PPE for healthcare personnel, but can be used for face covering for non-patient facing work or provided to visitors and others if they do not have face covering when entering the health ministry.
- If the KN95 does appear on the above lists, contact System Office Supply Chain prior to use.
Trinity Health received approval from an independent NIOS-certified lab for the following two models of KN95 respirators as substitutes for N95 respirators. The approved KN95 respirator can be used as an alternative to current N95 respirators. These models are available for procurement from the Mercy Medical Center Distribution Center via the standard procurement process.

<table>
<thead>
<tr>
<th>PeopleSoft Item#</th>
<th>Item Description</th>
<th>Manufacturer</th>
<th>Vendor</th>
<th>Manufacturer Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>786925</td>
<td>Mask N95 FLAT</td>
<td>SAN HUEI</td>
<td>ASP GLOBAL</td>
<td>SH3500</td>
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<tr>
<td>786926</td>
<td>MASK N95 CONE</td>
<td>SAN HUEI</td>
<td>ASP GLOBAL</td>
<td>SH9550</td>
</tr>
</tbody>
</table>

The KN95 respirator will have a different appearance than the US Made N95 respirators (See below)

- KN95 respirators are only available in one size so may not be suitable for everyone. In particular, staff who normally wear N95 respirator in a size “Small” may have difficulty obtaining a seal.
- K95 respirators are not intended for use in surgery or other high fluid areas
Important: For the KN95 and any other respirator, always perform a seal check before using. The illustration below is a helpful general guide:

**RESPIRATOR SEAL CHECK**

After you put on your respirator, perform a seal check by placing your hands over the facepiece, as shown below, and then exhaling gently. The seal is considered satisfactory if a slight positive pressure builds up inside the facepiece without air leaking from the seal. Air leakage is evidenced by the fogging of your glasses, a feeling of air trickling down your uncovered face, or a lack of pressure buildup under the facepiece.

If the respirator has an exhalation valve, cover the filter surface with your hands as much as possible and then inhale. The seal is considered satisfactory if the facepiece collapses on your face and you don’t feel air passing between your face and the facepiece.
If difficulty obtaining a seal with the KN95 Respirator

Example of knotted straps

- Mold respirator around face. Pay particular attention to metal piece on bridge of nose.
- If still loose:
  - Adjust the straps.
  - Consider use of an “ear saver” device or knotting the straps to pull the strings tighter.
- **Do not cut the straps.**
- Consult your local PPE Coach.

References: