

# KN95 Mask Frequently Asked Questions

May 2020

Premier understands the strain the COVID-19 pandemic is placing on healthcare providers, and that there is a shortage of PPE and other critical products available through typical supply chain channels.

We are continuing to see personal protective equipment (PPE) and other high-demand products available in very limited quantities. To that end, Premier is working to secure products for alternate site healthcare providers and to allocate them according to need with a data-driven approach. We are providing this information help keep you informed about our sourced products.

Both the CDC and FDA have [issued guidance](#) on usage of KN95 masks when N95 masks are not available during the COVID-19 pandemic. Premier is offering KN95 masks through S2S Global pursuant to the applicable guidance.

## Quick Facts about KN95 Masks Sourced through S2S Global:

- Sourced from **well-established, publicly traded manufacturers** in China, with **track records** for producing high-quality masks.
- S2S Global has reviewed **independent third-party testing** on all KN95 suppliers and each met or exceeded the 95% filtration standard.
- S2S Global representatives stationed at manufacturers' factories to **review product**.
- **Checked for fit by third-party inspectors** during the manufacturing process and before shipment when distributed through S2S Global for Premier members

Below are some frequently asked questions and answers surrounding KN95 masks.

## What are KN95 masks?

[According to the United States Centers for Disease Control and Prevention \(CDC\)](#), countries other than the United States approve face masks for occupational use according to country-specific standards. These products are evaluated using particle filtration testing methods that are similar to those used by the National Institute for Occupational Safety and Health (NIOSH).

The CDC includes KN95 masks manufactured in the People's Republic of China under "Respirator-Cartridge Units Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved Elastomeric Half-Facepiece Respirators".

## Are KN95 masks included in the list of alternatives when N95 masks are unavailable when treating patients with COVID-19?

Yes, [per the CDC](#), KN95 masks are included on the list of alternatives. [According to the FDA](#), for the duration of the COVID-19 pandemic, when NIOSH-approved filtering facepiece and elastomeric respirators are not available, the

FDA would not object to the importation and use of KN95 masks. We encourage you to reference your own internal policies to determine appropriate usage for your situation.

### **Are there guidelines available for use of KN95 masks?**

The [FDA encourages](#) that appropriate steps be taken to verify the authenticity of KN95 masks. It recommends to healthcare providers: “If you are a part of a group purchasing organization (GPO), you may want to contact the GPO staff to determine what communication they receive from their suppliers.”

Additionally, the CDC offers [advice for fit-testing masks](#) during infectious disease outbreaks.

### **What steps are being taken to ensure the quality and authenticity of the KN95 masks Premier is offering through S2S Global?**

The KN95 masks supplied for Premier members by S2S Global have been checked for fit and inspected by third-party inspectors during the manufacturing process and before shipment of product. S2S has created these additional steps, implemented above and beyond the typical S2S clinical review, to help meet the demand of customers.

The KN95 masks are offered pursuant to [CDC guidance on N95 masks and both the](#) FDA emergency use authorization (EUA) issued on Friday, April 3, 2020, and the May 7, 2020 update which revised the earlier guidance.

### **Where can I find additional information and guidance about N95 and KN95 masks and their usage when treating patients with COVID-19?**

The following resources are available for information and guidance on N95 and KN95 masks:

FDA: [FAQs on Shortages of Surgical Masks and Gowns](#)

FDA: [Emergency Use Authorizations](#)

CDC: [Strategies for Optimizing the Supply of N95 Respirators](#)

NY Times: [F.D.A. to Allow Use of KN95 Masks Approved by China](#)

S2S Global: [PPE Usage Best Practices](#)

Stockd: [COVID-19 Updates and PPE: Latest Alternative Resource Information](#)

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