

# Importing KN95 or N95 Masks

POSTED [APRIL 4, 2020](#)

The guidance around masks is continuing to expand and to be refined. The [U.S. Food and Drug Administration \(FDA\)](#) is now offering guidance for KN95 masks, which are a Chinese-equivalent of N95 masks. Scarbrough has compiled some information we have received from various organizations. Moreover, increased licensing on Chinese exports of medical supplies is now required and highly regulated by the [Chinese Government](#) [Click the link for details].

As we continue to receive more information, we will update this post. If you would like more information or need some guidance, our team of Licensed U.S. Customs brokers and Global Trade Experts are happy to help. [Please fill out this form](#) and continue reading!

In summary, N95 masks are allowed to be imported into the country with lowered restrictions if going to medical professional organizations, and the FDA can be disclaimed if the masks are for non-medical personnel and essential-needs companies, such as distribution centers and the like. The KN95 masks can also be brought in with lowered restrictions, but FDA is still being very specific on the types of masks eligible for these modified requirements. If you wish to use [The Scarbrough Group of Companies](#) to arrange the import cargo transport and/or U.S. Customs clearance, while guiding you through the FDA regulations, please [fill out this form for more guidance](#) and look at the checklist below.

You can also download this [FAQ Guide](#) we created to help field several of your questions.

---

## Checklist

If the items **ARE** intended for medical professionals: **FDA must be claimed.** Information required to file FDA normally includes:

1. Device Listing Number
2. Manufacturer Registration Number
3. Exporter Registration Number
4. 510(k) Premarket Number

© Jade Group International, LLC, All Rights Reserved | 143 Main Street West Bend, WI 53095  
+1 (262) 672-6373 | <https://masks.jademolds.com>

DISCLAIMER: Jade Group International, LLC believes that the information in this document provided by Scarborough is accurate and represents the best and most current information available at the time of its publication. Jade Group International, LLC makes no representations or warranties either express or implied for our KN95 non-surgical masks. Jade Group International, LLC will not be responsible for damages resulting from use of or reliance upon the information provided in this document.

## *EUA Approved Items*

However, if the item is listed as “approved for Emergency Use Authorization (EUA),” the above information becomes optional using a specific intended use code. It is still encouraged to be transmitted if the importer has it and this can be done through your U.S. Customs broker. Items authorized for EUA under current COVID-19 situation are diagnostic tests and masks/respirators. Specific approved models can be found [here](#), which includes masks that are both NIOSH-approved and non-NIOSH approved. [NIOSH is the [National Institute for Occupational Safety and Health](#)]

## *Non EUA Items*

Items being imported that are NOT listed as “approved for EUA” can still be imported with reduced restrictions using a different intended use code from the EUA. This intended use code flags the item as not part of an EUA, but shows that the item is subject to reduced restrictions due to a published enforcement discretion policy. This waives the same data points as the EUA, but includes items such as non-invasive remote monitoring devices, ventilators, and other accessories/respiratory devices. Information on specific Remote monitoring devices can be found [here](#). Information on the ventilators and similar accessories can be found [here](#).

While the United States has reduced enforcement, China has actually **increased** enforcement due to a mass of rejected shipments due to poor quality in various ports around the world.

For this reason, it is imperative that your shipper confirm in advance that it has all necessary approvals and licenses from the Chinese government, even if the United States does not need said information transmitted at the time of entry into the US.

The State of Missouri created a helpful guide for manufacturers interested in making personal protective equipment supplies. The state compiled information from the FDA and CDC, which is always evolving, so you will need to check direct with those agencies to keep up to date. You will likely be required to obtain federal certification to begin manufacturing and sales for most of the critically needed products. Check out the “[100 Million Masks Challenge](#)” initiative and guidance or download a helpful .pdf below.

[Download Medical Supplies Guidelines for Manufacturers \(.pdf\)](#)

## *FDA Guidance on KN95 Masks*

There are rumors that several delays and/or FDA refusals of KN95 mask shipments are occurring.

FDA is using the CDC [Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies](#) information to expand access, which includes KN95s. The Center for Devices is updating FDA's website to indicate this, but the approach is in effect now. Our instructions on the entry process for KN95s and others are below:

### **KN95, KN100, KP100, and KP95 Filtering Facepiece Respirators (Standard GB 2626-2006) NOT Under EUA**

CDC's [Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies](#) identifies respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators. CDC has determined these are suitable alternatives to provide protection during the COVID-19 response when supplies are short, when they conform to standards identified and provide a protection factor of at least 10. FDA does not object to importation and use of these respirators during the emergency.

FDA cannot confirm the performance and quality of face masks and respirators not under an EUA. The only person who can verify the authenticity is whoever issued it.

### **ACE Transmission Requirements for KN95s KN100, KP100, and KP95 NOT under EUA:**

Program Code: DEV

Processing Code: NED

Intended Use Code: 940.000 if the product is listed on [the CDC](#) website

081.001 if not listed on the CDC website

Product Code: 80N-ZJ

Use the [Product Classification](#) and [Product Code Builder](#)

## *COVID-19 Cargo Resolution Team Established by CBP*

U.S. Customs and Border and Protection (CBP) has established a COVID-19 Cargo Resolution Team (CCRT) as an effort to coordinate inquiries regarding the importation of medical supplies and personal protective equipment. The team is multidisciplinary to triage incoming inquiries, coordinate with affected ports and respond directly as appropriate.

© Jade Group International, LLC, All Rights Reserved | 143 Main Street West Bend, WI 53095  
+1 (262) 672-6373 | <https://masks.jademolds.com>

DISCLAIMER: Jade Group International, LLC believes that the information in this document provided by Scarborough is accurate and represents the best and most current information available at the time of its publication. Jade Group International, LLC makes no representations or warranties either express or implied for our KN95 non-surgical masks. Jade Group International, LLC will not be responsible for damages resulting from use of or reliance upon the information provided in this document.

Due to the high volume of inquiries, CBP has created a new Web Portal to tackle questions. You can view it here: <https://imports.cbp.gov/>.

**Types of inquires that should be sent to the mailbox are:**

- Facilitation requests from other government agencies and private industry
- General inquiries regarding the import of medical instruments

To assist your U.S. Customs broker or CBP in expediting the release of COVID-19 relief materials, please include as much data about the shipment as possible. Ideally, this will include the following:

- Shipment information: manifest or air waybill numbers, tracking numbers, entry numbers, mode of transport information
- Conveyance information: carrier name, mode of transportation, flight number, vessel/voyage number, port of arrival, port of entry
- Cargo description: complete description of the goods being shipped
- Country information: country of manufacture, country of export
- Parties involved: names and locations of manufacturers, shippers, importers, and consignees

**FDA COVID-19 Support Page**



© Jade Group International, LLC, All Rights Reserved | 143 Main Street West Bend, WI 53095  
+1 (262) 672-6373 | <https://masks.jademolds.com>

DISCLAIMER: Jade Group International, LLC believes that the information in this document provided by Scarborough is accurate and represents the best and most current information available at the time of its publication. Jade Group International, LLC makes no representations or warranties either express or implied for our KN95 non-surgical masks. Jade Group International, LLC will not be responsible for damages resulting from use of or reliance upon the information provided in this document.

## About Scarbrough

[The Scarbrough Group of Companies](#), headquartered in Kansas City with local presence in every major port in the world, is a complete international and domestic supply chain service provider, offering U.S., Mexican, and Canadian Customs brokerage, Import & Export Transportation Solutions, Domestic brokerage and asset-based trucking, Warehouse fulfillment and distribution services, Trade Compliance Consulting, Large Equipment and Project Cargo moves, as well as Parcel Audit Savings. Scarbrough is widely known for its trade experts, training, personalized customer service, customized solutions, and data analytics tools. Since 1984, Scarbrough has continued to satisfy its clients by following its motto on a daily basis: **“It is our job to make your job easier.”** Moreover, our team of experts is available at your disposal. We offer free consultations on any topic from supply chain optimization and duty savings opportunities to the basics, helping to guide new importers and exporters as they jump into the world of global trade. [Contact us now.](#)