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Importing Masks FAQ

1. Do importers need to have a license in order to import masks into the U.S.?
 - a. No import license is required to bring masks into the U.S., although if your shipper is located in China, it will need [approval from Chinese authorities](#).
2. If my shipper is located in China, what is required for export authorization?
 - a. Exports of the products from China require certification from authorized testing laboratories, copies of the manufacturer's business license, and the manufacturer's certificate from China's National Medical Products Administration
3. If my goods **are not** intended for medical professionals, is FDA required? Is an importer required to file FDA on the U.S. Customs entry if the product is not intended for medical use?
 - a. No. If your masks are intended for non-medical personnel such as industrial work, warehouse work, or personal use, FDA is not required to be transmitted and can be disclaimed. Scarbrough will take care of this when submitting the entry to U.S. Customs.
4. If my goods **are** intended for medical use, what is required?
 - a. If the masks are intended for sale or donation to healthcare professionals or intended for medical use, FDA is required. This includes (but is not limited to) hospital workers, home care specialists, nursing home staff, etc.
 - b. The FDA information will be transmitted by Scarbrough on your Customs entry
 - c. Required FDA info: keep reading.
5. What if I don't know who the end user will be on the masks I am importing?
 - a. If you do not know if the masks will end up in the hands of medical professionals, you should file FDA information. In other words, if you cannot adequately verify that your masks will be used for medical or non-medical purposes, you should assume they will be used for medical purposes at some point. Scarbrough recommends filing FDA.
6. What is Emergency Use Authorization?
 - a. Emergency Use Authorization (EUA) grants FDA the authority to waive certain requirements of importing goods into the US at times of severe need. In short, it makes it easier for importers to bring in goods that are in critical need with less restriction than normal. This includes things like company and item registration which normally needs to be done in advance of importing.
 - b. For example, if you are importing masks for medical-use during the COVID-19 pandemic, the normally required FDA registration at manufacturing site is waived. [See below]

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7. When is the current EUA on masks in effect?
 - a. While the EUA on masks has been modified and updated several times, it was initially implemented on March 2, 2020 after it was determined that COVID-19 posed a significant risk to the health of US Citizens. At present, there is not a specific end date as to when the EUA will be removed, only that it will be removed at such a time that COVID-19 is no longer seen as posing a significant health risk to US citizens. When this happens, all registration and other requirements which are currently waived under the EUA will once again be in place.

8. Do importers need to be **registered** with the FDA in order to import masks into the US?
 - a. At present, no. Under the Emergency Use Authorization, many registrations and filing requirements are waived due to the critical need for these supplies. One such requirement is that the importer does not currently need to be registered with the FDA as an importer of medical devices. A guide on who normally has to be registered can be found [here](#).
 - b. Note: Claiming FDA and Registering with the FDA are 2 different things. Scarbrough will claim the FDA on your U.S. Customs entry. This is still required if the item is intended for Medical-use.

9. Do shippers or manufacturers need to be **registered** with the FDA in order to export to the US?
 - a. At present, their registration number (both exporter and manufacturer) does not need to be reported to the FDA at time of entry for EUA-approved masks, although if they are producing FDA-approved masks, they do likely have this information. If you have it, FDA encourages you to transmit it with your FDA information.

10. Do I need a Device Listing Number (LST) for the mask?
 - a. At present, the LST is not required to be transmitted to FDA for EUA-approved masks. The mask likely does have an LST number if it is an FDA/NIOSH-approved mask, but this number is not presently required to be reported to FDA at time of entry. If you have it, FDA encourages you to transmit it with your FDA information.

11. Do I need a 510(k) Premarket Notification Number (PM#) for the masks?
 - a. At present, a PM# is not required to be transmitted to FDA for EUA-approved masks. The mask likely does have a PM# if it is an FDA/NIOSH-approved mask, but this number is not presently required to be reported to FDA at time of entry. If you have it, FDA encourages you to transmit it with your FDA information.

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12. What models of masks are covered by the EUA?
 - a. There are two categories of masks covered by the EUA: NIOSH-approved and non-NIOSH-approved masks. A full list of NIOSH-approved masks can be found [here](#) and includes, among many others, N95 and KN95 masks. A full list of non-NIOSH-approved masks can be found [here](#) and includes many models of mask that do not offer the same level of protection as NIOSH-approved masks, but have been determined to be sufficient to reduce the spread of COVID-19.

13. Is there a limit to the number of masks that can be imported at this time?
 - a. At present, Scarbrough is not aware of any limitations on the number of masks being brought into the US. The purpose of the EUA is to increase access to these critical PPE items during this health crisis, so it makes sense that the US is not restricting the number being brought in either.

14. What if I am using Fedex or UPS for the transportation, and Scarbrough for U.S. Customs entry?
 - a. **Scarbrough can handle the transportation, U.S. Customs entry and final delivery. Please email us for pricing!** But, if you choose to move with UPS & FedEx, they require a Broker Select Form to be filled out. [Download Fedex BSO](#) or ask UPS for BSO form.

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 FDA regulations, [fill out this form for more guidance](#).

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.”** [Contact us now](#).

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