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CSMS #42124872 -Information for Filing Personal Protective Equipment and Medical Devices During COVID-19

U.S. Customs and Border Protection sent this bulletin at 03/23/2020 04:17 PM EDT



**U.S. Customs and
Border Protection**

Cargo Systems Messaging Service

CSMS #42124872 -Information for Filing Personal Protective Equipment and Medical Devices During COVID-19

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The U.S. Food and Drug Administration is providing instruction to the import community regarding the submission of entry information for personal protective equipment and certain other devices. Following the instructions below will help facilitate the import process for all; especially for products related to the Coronavirus Disease-2019 (COVID-19) public health emergency. It is in the best interest of the U.S. to facilitate and expedite the importation of products into the U.S. market that address immediate, urgent public health needs.

For further information regarding entry submission requirements, see the FDA Supplemental Guidance for ACE at <https://www.cbp.gov/sites/default/files/assets/documents/2020-Mar/FDA%20Supplemental%20Guide%20Release%202.5.1%202018%200410.pdf>.

1. Non-FDA-regulated general purpose personal protective equipment (masks, respirators, gloves, etc.):

Personal protective equipment for general purpose or industrial use (that is, products that are not intended for use to prevent disease or illness) is not regulated by FDA.

For these types of products, entry information should not be transmitted to FDA. At the time of entry for these products, Importers should transmit entry information to US Customs and Border Protection (CBP) using an appropriate HTS code with no FD Flag; or using an appropriate HTS code with an FD1 flag and do a 'disclaim' for FDA.

2. Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA)

When importing such products, entry information should be submitted to FDA; however reduced FDA information is required for review.

At the time of entry, Importers should transmit an Intended Use Code of 940.000: Compassionate Use/Emergency Use, and an appropriate FDA product code.

Below is a list of products and the appropriate product codes that are currently authorized by an EUA:

- Diagnostic tests: QPK, OTG, QKO, QJR
- Masks/Respirators: NZJ

Questions regarding appropriate product coding can be submitted to FDA at: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Requests for Emergency Use Authorization can be submitted to FDA at: CDRH-EUA-Templates@fda.hhs.gov (for diagnostic devices) and CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov (for non-diagnostic devices)

3. Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

When importing such devices, entry information should be submitted to FDA.

At the time of entry, Importers should transmit an Intended Use Code of 081.006: Enforcement discretion per final guidance, and an appropriate FDA product code.

Below is a listing of guidance documents that have been issued for specific products related to COVID-19, which contain product codes within the scope of each guidance:

- [Non-Invasive Remote Monitoring Devices](#)
- [Ventilators and Accessories and Other Respiratory Devices](#)

A [full list of all guidance documents related to COVID-19](#) is also available on FDA's website.

All questions regarding these instructions, or to resolve entry issues for shipments can be submitted to FDA at: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov or 301-796-0356.



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