



# FedEx Regulatory Alerts & Updates

## Regulatory Alert Update: FDA Import Requirements for Personal Protective Equipment

April 23, 2020

### BACKGROUND

The U.S. Food and Drug Administration (FDA) has provided instruction to the import community via CSMS messages #42124872, #42168200, #42272898 and #42448725 regarding the submission of FDA entry information for certain personal protective equipment (PPE) and other devices. Following the FDA's instructions will help facilitate the import process for products related to the Coronavirus Disease 2019 (COVID-19) public health emergency.

Note: The circumstances surrounding the COVID-19 public health emergency are very fluid and subject to rapid changes.

### WHAT IS NEW?

In CSMS message #42448725 issued on April 21, 2020, the FDA provided updated lists of products that are covered by an Emergency Use Authorization (EUA) and those where an enforcement discretion policy has been published in a guidance document.

The new products covered by an EUA include non-NIOSH-approved respirators (classified under FDA product code 80QKU), face shields, respirator decontamination systems, extracorporeal blood purification devices, infusion pumps, ventilators and diaphragmatic pacing simulator systems.

Qualifying products covered by an EUA are designated by the FDA intended use code 940.000.

The new products that have an enforcement discretion policy published in a guidance document include Telethermographic Systems, Remote Ophthalmic Assessment and Monitoring Devices, Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices, Infusion Pumps and Accessories, and Digital Health Devices for Treating Psychiatric Disorders.

Qualifying products that are covered by an enforcement discretion policy are designated by FDA intended use code 081.006.

There is a link included in the Resources section below that leads to the full list of FDA guidance documents. Further information regarding which product codes fall within the scope of each guidance can be found there.

For any questions regarding these instructions or requests for product code assistance, contact the FDA via email at [COVID19FDAIMPORTINQUIRIES@fda.hhs.gov](mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov) or by telephone at (301) 796-0356.

## Q & A

### Q1: How do I find my medical device's FDA product code?

A1: The FDA has a web page dedicated to product code classification which provides information about how to find a product code. A link to this site is provided in the Resources section.

Further questions regarding appropriate product coding or intended use can be submitted to FDA at: [COVID19FDAIMPORTINQUIRIES@fda.hhs.gov](mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov).

## RESOURCES

CSMS message #42448725:

[https://content.govdelivery.com/bulletins/gd/USDHSCBP-287b755?wgt\\_ref=USDHSCBP\\_WIDGET\\_3?utm\\_source=google&utm\\_medium=google&utm\\_term=\(not%20provided\)&utm\\_content=undefined&utm\\_campaign=\(not%20set\)&gclid=undefined&dclid=undefined&GAID=847603829.1520374685](https://content.govdelivery.com/bulletins/gd/USDHSCBP-287b755?wgt_ref=USDHSCBP_WIDGET_3?utm_source=google&utm_medium=google&utm_term=(not%20provided)&utm_content=undefined&utm_campaign=(not%20set)&gclid=undefined&dclid=undefined&GAID=847603829.1520374685)

CSMS message #42272898:

[https://content.govdelivery.com/bulletins/gd/USDHSCBP-2850882?wgt\\_ref=USDHSCBP\\_WIDGET\\_2](https://content.govdelivery.com/bulletins/gd/USDHSCBP-2850882?wgt_ref=USDHSCBP_WIDGET_2)

CSMS message #42124872:

[https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt\\_ref=USDHSCBP\\_WIDGET\\_2%3Futm\\_source%3Dsearch.usa.gov&utm\\_medium=search.usa.gov&utm\\_term=undefined&utm\\_content=undefined&utm\\_campaign=%28not+set%29&gclid=undefined&dclid=undefined&GAID=102834089.1540533732](https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt_ref=USDHSCBP_WIDGET_2%3Futm_source%3Dsearch.usa.gov&utm_medium=search.usa.gov&utm_term=undefined&utm_content=undefined&utm_campaign=%28not+set%29&gclid=undefined&dclid=undefined&GAID=102834089.1540533732)

CSMS message #42168200:

<https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2836f88>

Link to all FDA COVID-19 guidance documents:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>

FDA Personal Protective Equipment (PPE) web page:

<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control>

FDA Product Code Finder web page:

<https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database>

Link to RegAlert 20-050-U FDA Import Requirements for Personal Protective Equipment:

[https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert\\_20-050\\_FDA\\_Import\\_Requirements\\_for\\_Personal\\_Protective\\_Equipment.pdf](https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert_20-050_FDA_Import_Requirements_for_Personal_Protective_Equipment.pdf)

Link to RegAlert 20-051-U FDA Import Requirements for Personal Protective Equipment:

[https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert\\_20-051\\_FDA\\_Update-Import\\_Requirements\\_for\\_Personal\\_Protective\\_Equipment.pdf](https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert_20-051_FDA_Update-Import_Requirements_for_Personal_Protective_Equipment.pdf)