



## Röhlig **USA NEWS**

In an effort to lessen the damage caused by the Corona Virus, Customs has made an attempt to be more flexible to minimize the damages caused by lack of equipment and economic hardships related to the virus this week.

Although they do not offer complete guidance, they are all we have at the moment. Please see the two messages provided this week.

It is noteworthy, that although there are lessened restrictions for importation of much needed medical supplies, it is our responsibility in the trade community in order ensure the supplies for our healthcare workers are not substandard and dangerous.

To address the guidance for additional time for duty payments, the feedback I have gotten is that the requests are not being answered and I have not heard of confirmation of any relief granted. It appears that the program has ended before it really ever began. But this is a fluid situation.



# U.S. Customs and Border Protection

## Cargo Systems Messaging Service

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### **CSMS #42168200 - Information for Filing Personal Protective Equipment and Medical Devices During COVID-19**

The U.S. Food and Drug Administration is providing an *update to CSMS message 42124872* for instructions 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.

#### **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.

#### **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 Device*, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional in ACE.

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

- Diagnostic tests: 83QKP, 83QKO, 83QJR
- Masks/Respirators: 80NZJ

[A full list of Emergency Use Authorizations](#) currently in place for the COVID-19 emergency is also available on FDA's website. Please check this site regularly for current information on products authorized by an EUA.

**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 Intended Use Code 081.006: *Enforcement discretion per final guidance*, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional in ACE.

Below is a listing of guidance documents that have been issued for specific products related to COVID-19, which reference applicable product codes and policy for those products:

- [Face Masks and Respirators](#)
- [Ventilators and Accessories and Other Respiratory Devices](#)
- [Non-Invasive Remote Monitoring Devices](#)
- [Diagnostic Tests](#)

A [full list of all guidance documents related to COVID-19](#) is also available on FDA's website. Please check this site regularly for current information on these and other product areas. This message will be updated to specifically include additional guidance as it becomes available.

All questions regarding these instructions, product code assistance for these products, or to resolve entry issues can be submitted to FDA at: [COVID19FDAIMPORTINQUIRIES@fda.hhs.gov](mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov) or 301-796-0356.

Step-by-Step instructions on how to register and list can be found on our website at: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>.

For additional assistance with completing initial registration, firms should contact the CDRH Registration and Listing Helpdesk at [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov).

For assistance with paying the annual registration user fee, firms can reach out to the User Fee Helpdesk at [userfees@fda.gov](mailto:userfees@fda.gov).

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

As usual, FDA may request additional information on a case-by-case basis for making its final admissibility decision.

## **Cargo Systems Messaging Service**

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### **CSMS #42179545 - Additional Guidance for Entry Summary Payments Impacted by COVID-19 March 27, 2020**

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In a continued effort to work with the trade community through the national emergency challenges resulting from the COVID-19 pandemic, U.S. Customs and Border Protection (CBP) issued Cargo Systems Messaging Service (CSMS) message 42097586 on 3/20/2020, requesting case-by-case need for additional days for payment of estimated duties, taxes and fees.

In addition, on 3/26/2020, CBP issued CSMS message 42161666 to (a) notify the trade community that CBP is no longer accepting requests for additional days for payment, and (b) provide guidance to Brokers (including brokers that made requests on behalf of

importers), Importers and Sureties on processing the universe of entries affected by the previous message.

This message is to provide additional language for CSMS message 42161666 based on questions received since issuance. **Additional language is in bold text.**

Message 42161666 applies to **ALL** parties who have submitted a request to CBP in writing for additional days for payments, in response to CSMS 42097586, **from 3/20/2020 through 3/26/2020, whether or not a response was received from CBP.**

**Timeframe For Payment:**

**ALL** single payments, daily and periodic monthly statement payments of estimated duties, taxes and fees that should have been tendered from 3/20/2020 through 3/26/2020, **but were deferred based on CSMS message 42097586**, must be initiated by 3/27/2020.

If a trade member did not pay CBP for estimated duties, taxes and fees due 3/20/2020 through 3/26/2020, payment should be initiated via FedWire or ACH credit by 3/27/2020.

**Payment Instructions:**

**If ACH Debit Authorizations were stopped by your financial institution, FedWire should be used to submit payments for amounts owed between 3/20/2020 and 3/26/2020 as CBP is not able to re-debit your account.** If paying via FedWire, please follow the attached instructions. For payment of Periodic Monthly Statement, include the Periodic Monthly Statement numbers in the Originator to Beneficiary Information Line 2. If paying a daily statement please enter the daily statement number. If paying multiple statements, please send the list of those statements to [debitvoucherteam2@cbp.dhs.gov](mailto:debitvoucherteam2@cbp.dhs.gov). Alternatively, parties who are current ACH Credit participants may pay via ACH Credit following normal business practices.

Please Note: Although the temporary option was provided to extend payment due dates, if the money was withdrawn from the account, these funds are legally owed to CBP and a refund will not be issued. Trade users need to work with their financial institutions to ensure that future ACH debit and ACH credit payments to CBP are processed appropriately.

**Future Payments:**

**ALL single payments, daily statement and periodic monthly statement payments of estimated duties, taxes and fees due to CBP on or after 3/27/2020 should be made in accordance with normal business practices. CBP is no longer accepting deferral requests.**

**Additional Information:**

CBP is continuing to work with our federal and private sector partners to identify

appropriate mechanisms to manage the operational impacts of COVID-19. The trade community should monitor CSMS for additional changes related to COVID-19.

Policy questions should be directed to the Office of Trade, Trade Policy and Programs at [OTentrysummary@cbp.dhs.gov](mailto:OTentrysummary@cbp.dhs.gov).

If you have any questions please reach out to your local Rohlig contact or [Chris.Lundy@Rohlig.com](mailto:Chris.Lundy@Rohlig.com)