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Personal Protective Equipment (PPE) Import Guidelines

PRODUCT	IMAGE	TARIFF #	DUTY RATE	CHINA TARIFF	FDA REQUIREMENTS	EMERGENCY USE AUTORIZATION
FACE MASK (NON-MEDICAL)		9020.00.6000	2.5%	0%	NONE	**FDA INFO NOT REQUIRED**
FACE MASK (NON MEDICAL)		6307.90.9889	7%	0%	NONE	**FDA INFO NOT REQUIRED**
3 PLY FACE MASK (NON-MEDICAL)		6307.90.9889	7%	0%	NONE	**FDA INFO NOT REQUIRED**
FACE MASK (N95)		6307.90.9889	7%	0%	51) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**NOT ALL FDA INFO IS REQURED** – COUNTRY SPECIFIC EUA AUTHORIZED - Provide as much info as possible

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FACE MASK (KN95) from CHINA		6307.90.9889	7%	0%	Please see guidance below "KN95, KN100, KP100, and KP95 Filtering Facepiece Respirators (Standard GB 2626-2006) NOT Under EUA "	**EUA INFORMATION FOUND HERE**
DIAGNOSTIC TESTS		3002.12 3002.13 3002.14 3002.15 3822.00 9027.80 (25% China tariff)	FREE	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**NOT ALL FDA INFO IS REQURED** – Provide as much info as possible
Mercury Thermometers (medical)		9025.11.2000	FREE	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**See FDA requirements listed below**
Digital or Infrared Thermometers (medical)		9025.19.8040	FREE	25% (0% if value < $11)	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**See FDA requirements listed below**

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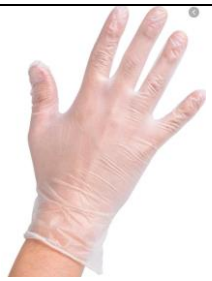
Infrared Thermometer (medical)		9025.19.8040	FREE	25% (0% if value < $11)	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**See FDA requirements listed below**
SAFETY GOOGLES (MEDICAL)		9004.90.0000	2.5%	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	
FACE SHIELD		3926.90.9990	5.3%	7.5%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**UNDER EUA -** *NOT ALL FDA INFO IS REQUIRED –* - See more info below
PLASTIC GLOVES (NON-MEDICAL)		3926.20.1020	0%	0% from China	N/A	**FDA INFO NOT REQUIRED**

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SURGICAL GLOVES (MEDICAL)		4015.11.0110 (natural rubber) 4015.11.0150 (non-natural rubber)	FREE	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	
OTHER RUBBER GLOVES (NITRILE) *(NON-MEDICAL)*		4015.19.1010	3%	0%	N/A	
OTHER RUBBER GLOVES (NITRILE) (*MEDICAL*)		4015.19.0550	0%	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	
HAND SANITIZER Should have *benzalkonium chloride*, *Alcohol* (ethyl alcohol or ethanol, 60-95%), *isopropyl alcohol* (70 to 91.3%) to be considered an OTC hand sanitizer.		3824.99.9297	5%	25% IF FROM CHINA	1.Drug Listing Number (Formerly NDC Number) 2.Drug Registration Number (or DUNS#) 3. TSCA form	

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All others must apply for new drug registration with FDA.						
ISOLATION GOWN (PLASTIC)		3926.20.9050	5%	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**Under EUA** – NOT ALL FDA INFO IS REQUIRED – provide as much info possible.
ISOLATION SUIT (PLASTIC)		3926.20.9050	5%	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**Under EUA** – NOT ALL FDA INFO IS REQUIRED – provide as much info possible.
NON-WOVEN DISPOSABLE APPAREL		6210.10.5000	0%	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**Under EUA** – NOT ALL FDA INFO IS REQUIRED – provide as much info possible.
SHOE COVERS (POLYETHYLENE)		6307.90.9889	7%	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	

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ALCOHOL WIPES (NON AROMATIC)		3808.94.5000	5%	25% IF FROM CHINA	1.Drug Listing Number (Formerly NDC Number) 2.Drug Registration Number (or DUNS#) 3. TSCA form	
ALCOHOL WIPES (AROMATIC)		3808.94.1000	6.5%	25% IF FROM CHINA	1.Drug Listing Number (Formerly NDC Number) 2.Drug Registration Number (or DUNS#) 3. TSCA form	
VENTILATORS		9019.20.0000	FREE	0%	1) Device foreign manufacturer # 2)Device foreign exporter# 3)Device listing #	**EUA NEEDS TO BE REQUESTED if not listed in Appendix B**

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CBP GUIDANCE ON CLASSIFICATION

HS classification reference for Covid-19 medical supplies

Note: this list is provided as an indicative list only. It does not have legal status.

Categories	Product names	Brief info	HS Classification	Center
I. COVID 19 Test kits Instruments and apparatus used in Diagnostic Test	COVID 19 Test kits	Diagnostic reagents based on polymerase chain reaction (PCR) nucleic acid test	3822.00	Pharmaceuticals, Health & Chemicals
	COVID 19 Test kits	Diagnostic reagents based on immunological reactions	3002.15	Pharmaceuticals, Health & Chemicals
	COVID 19 Diagnostic Test instruments and apparatus	Instruments used in clinical laboratories for In Vitro Diagnosis	9027.80	Machinery
II. Protective garments and the like	**Face and eye protection**			
	* Textile face-masks, **without** a replaceable filter or mechanical parts, including surgical masks and disposable face masks made of non woven textiles.		6307.90	Apparel, Textiles & Footwear
	* Gas masks **with** mechanical parts or replaceable filters for protection against biological agents . Also includes such masks incorporating eye protection or facial shields.		9020.00	Machinery
	* Protective spectacles and goggles		9004.90	Consumer Products & Mass Merchandising
	* Plastic face shields (covering more than the eye area)		3926.20	Consumer Products & Mass Merchandising
	Gloves			
	* Plastic gloves		3926.20	Consumer Products & Mass Merchandising
	* Surgical rubber gloves		4015.11	Apparel, Textiles & Footwear
	* Other rubber gloves		4015.19	Apparel, Textiles & Footwear
	* Knitted or crocheted gloves which have been impregnated or covered with plastics or rubber		6116.10	Apparel, Textiles & Footwear
	* Textile gloves that are not knitted or crocheted		6216.00	Apparel, Textiles & Footwear
	Other			
	* Disposable hair nets		6505.00	Apparel, Textiles & Footwear
	* Protective garments for surgical/medical use **made up of felt or nonwovens whether or not impregnated, coated, covered or laminated** (fabrics of heading 56.02 or 56.03). This includes spun-bonded garments.		6210.10	Apparel, Textiles & Footwear
	* Other protective garments of textiles of rubberised textile fabrics or woven fabrics that are impregnated, coated, covered or laminated fabrics of heading s 59.03, 59.06 or		6210.20 6210.30	Apparel, Textiles &

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	59 .0 7) Actual classification will depend on type of garment and if for males or females. Example: a unisex full body woven suit impregnated with plastics would be classified under 6210.50 ~ Other women's or girls' garments	6210.40 6210.50	Footwear
	* Protective garments made from plastic sheeting	3926.20	Consumer Products & Mass Merchandising

III. Thermometers	Liquid filled thermometer for direct reading	Includes standard "Mercury in glass " clinical thermometer.	9025.11	Machinery
	Other thermometers	For example, digital thermometers , or infrared thermometers for placing on the forehead.	9025.19	Machinery
IV. Disinfectants/ Sterilization products	Alcohol solution	Undenatured , containing by volume 80% or more ethyl alcohol	2207.10	Agriculture & Prepared Products
	Alcohol solution	Undenatured, 75% ethyl alcohol	2208.90	Agriculture & Prepared Products
	Hand sanitizer	A liquid or gel generally used to decrease infectious agents on the hands, alcohol based type	3808.94	Pharmaceuticals, Health & Chemicals
	Other disinfectant preparations	Put up in forms or packings for retail sale such as rubs and wipes impregnated with alcohol or other disinfectants.	3808.94	Pharmaceuticals, Health & Chemicals
	Medical, surgical or laboratory sterilizers	Function by steam or boiling water	8419.20	Machinery
	Hydrogen peroxide **in bulk**	Bulk H2O2 whether or not solidified with urea.	2847.00	Pharmaceuticals, Health & Chemicals
	Hydrogen peroxide **presented as a medicament**	H2O2 put up for internal or external use as a medicine , including as an antiseptic for the skin. Only covered here if in measured doses or in forms or packings for retail sale (including directly to hospitals) for such use.	3004.90	Pharmaceuticals, Health & Chemicals
	Hydrogen peroxide **put up in disinfectant preparations for cleaning surfaces**	H2O2 put up as cleaning solutions for surfaces or apparatus.	3808.94	Pharmaceuticals, Health & Chemicals
	Other chemical disinfectants	Put up in forms or packings for retail sale as disinfectants or as disinfectant preparations , containing alcohol, benzalkonium chloride solution or peroxyacids, or other disinfectants.	3808.94	Pharmaceuticals, Health & Chemicals

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V. Other medical devices	Computed tomography (CT) scanners	Uses a rotating X ray machine to image thin slices of the body to diagnose diseases such as pneumonia.	9022.12	Pharmaceuticals, Health & Chemicals
	Extracorporeal membrane oxygenation (ECMO)	Provides prolonged cardiac and respiratory support by removing blood from the person's body and artificially removing the carbon dioxide and oxygenating red blood cells.	9018.90	Pharmaceuticals, Health & Chemicals
	Medical ventilators artificial respiration apparatus)	Provide s mechanical ventilation by moving breathable air into and out of the lungs	9019.20	Pharmaceuticals, Health & Chemicals
	Other oxygen therapy apparatus including oxygen tents	As well as complete oxygen therapy apparatus, this subheading also covers recognisable parts of such systems.	9019.20	Pharmaceuticals, Health & Chemicals
	Patient monitoring devices apparatus	Electrical or electronic equipment for the observation of a disease, condition or one or several medical parameters over time. This includes such devices as pulse oximeters or bedside monitoring stations used for continuous monitoring of various vital signs. (Note: this does not include devices more specifically covered elsewhere e.g. electro-cardiographs (9018.11) or electronic thermometers (9025.19).)	9018.19	Pharmaceuticals, Health & Chemicals
VI. Medical Consumables	Wadding, gauze, bandages , cotton sticks and similar articles	Impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical use.	3005.90	Pharmaceuticals, Health & Chemicals
	Syringes, with or without needles		9018.31	Pharmaceuticals, Health & Chemicals
	Tubular metal needles and needles for sutures		9018.32	Pharmaceuticals, Health & Chemicals
	Needles, catheters, cannulae and the like		9018.39	Pharmaceuticals, Health & Chemicals
	Intubation kits		9018.90	Pharmaceuticals, Health & Chemicals

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	Paper bed sheets		4818.90	Consumer Products & Mass Merchandising

Emergency Use Authorization (EUA)

Emergency Use Authorization (EUA) means that not all FDA information is required for importation. List of products for which EUA has been issued can be found at

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

These include:

- Stryker Sustainability Solutions VHP Decontamination System
- Gowns and Other Apparel
- STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers
- COVID-19 Airway Management Isolation Chamber (CAMIC)
- Duke Decontamination System
- Protective Barrier Enclosures
- Sterilucent, Inc. Sterilization System
- Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle
- Advanced Sterilization Products (ASP) STERRAD Sterilization System
- STERIS Sterilization Systems for Decontamination of N95 Respirators
- Face Shields
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China
- Battelle Decontamination System
- NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency
- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

CSMS #42448725

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.

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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 certain product codes authorized by an EUA. A complete list of product codes may be found in corresponding enforcement policy guidance documents identified below.

- Non-NIOSH-Approved Respirators: 80QKU
- NIOSH-Approved Respirators
- Face Masks (Non-Surgical)
- Diagnostic Tests Kits
- Ventilators
- Face Shields
- Respirator Decontamination Systems
- Extracorporeal Blood Purification Devices
- Infusion Pumps
- Ventilators
- Diaphragmatic Pacing Simulator Systems

A full list of Emergency Use Authorizations currently in place for the COVID-19 emergency is also available on the FDA's website. Please check this site regularly for current information on products authorized by an EUA. Future updates to this message will only identify new EUAs in this section. The full list will be provided on the FDA website: Information for Filing Personal Protective Equipment and Medical Devices During COVID-19.

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:

- Telethermographic Systems
- Remote Ophthalmic Assessment and Monitoring Devices
- Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices
- Infusion Pumps and Accessories
- Digital Health Devices for Treating Psychiatric Disorders
- Clinical Electronic Thermometers
- Gowns, Other Apparel, and Gloves
- Sterilizers, Disinfectant Devices and Air Purifiers
- Face Masks and Respirators
- Non-Invasive Remote Monitoring Devices
- Ventilators and Accessories and Other Respiratory Devices
- Diagnostic Tests

A full list of all guidance documents related to COVID-19 is also available on FDA's website. For guidance applicable to medical devices, you may filter by the medical device product area and display all entries. Please check this site, as well as Information for Filing Personal Protective Equipment and Medical Devices During COVID-19, regularly for current information on these and other product areas.

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Cloth Face Covering (Face Mask):

EUA 's scope is limited to the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as HCP in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of the SARSCoV-2 during the COVID-19 pandemic. The facemasks are not intended to be used by HCPs as PPE, meaning they are neither substitutable for respiratory protective devices such as filtering face piece respirators, nor for surgical face masks. This use is consistent with face masks regulated as Class I 510(k)-exempt face masks under 21 CFR 878.4040.

Authorized Face Masks

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);
2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and 6. The product is not labeled for use in high risk aerosol generating procedures

More info can be found at https://www.fda.gov/media/137121/download

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More on N95 Face Masks:

This is a very fluid situation and the guidance can change at any time. Refer to the most current CSMS 42272898 Information for filing Personal Protective Equipment and Medical Devices during COVID 19. Please monitor the Coronavirus FDA page for the latest information: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19. FDA has also established an N95 Respirators and Surgical Masks (Face Masks) website.

On March 25, 2020, FDA released Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. Please review this guidance document if you are importing these products. Here are a few of the key points from the guidance document related to face masks:

Other face masks and filtering facepiece respirators (FFRs) that are marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is not required, and all the other requirements of the FD&C Act do not apply to manufacturers, importers, and distributors of these products. Face Masks and N95 Respirators Not Intended for a Medical Purpose are not required to be transmitted to FDA and can be disclaimed.

Table 1

Classification	Device Type	Product Code
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT
	Surgical Apparel Accessory (Face Shields)	LYU
21 CFR 880.6260	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	ORW
21 CFR 880.6260	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	NZJ

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Can respirators approved under standards used in other countries, such as *KN95*, be used in the US during the COVID-19 pandemic?

Yes. The FDA is working diligently to mitigate any potential shortages in the supply chain and taking action to assure health care personnel on the front lines have sufficient supplies of respiratory protective devices. The FDA concluded, based on the totality of scientific evidence available, that certain imported respirators that are not NIOSH-approved are appropriate to protect the public health or safety.

On March 24, 2020, the FDA issued an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators. Under this EUA, among other criteria, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea and Mexico who have similar standards to NIOSH. The FDA did not list KN95 respirators made per China's standards in this EUA because of concerns about fraudulent products listed as KN95s. On April 3, 2020, in response to continued respirator shortages, the FDA issued a new EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

A disposable non-NIOSH-approved respirator manufactured in China that meets one of the following criteria for authentication is eligible for authorization under this EUA:

1. It is manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA;

2. It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA; or

3. It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA

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FDA will need to confirm the criteria is met before authorizing the respirator under this EUA. The process for manufacturer's requesting for authorization is further outlined in the following notice - https://www.fda.gov/media/136664/download

The FDA also issued guidance to provide a policy to help expand the availability of general use face masks for the general public and respirators for health care professionals during this pandemic. The guidance applies to KN95 respirators as well. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN95 respirators, if they are on the Centers for Disease Control and Prevention (CDC) list of respirator alternatives during the COVID-19 pandemic. Although not required, if a KN95 respirator does not have an EUA, importers may want to take appropriate steps to verify authenticity of these products.

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Gowns and Other Apparel:

Emergency Use Authorization (EUA) has been issued for gowns, but is limited to the use of certain gowns and other apparel for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to protect both HCP and patients from the transfer of SARS-CoV-2 in low or minimal risk level situations to prevent the spread of COVID19.

The *types of gowns* and other apparel included in the scope of this EUA are those that are identified in the "Device Type" column in the table below.

Table 1. Gowns and Other Apparel

Classification Regulation	Device Type	Product Code[13]	Class
21 CFR 878.4040	Conductive shoe and shoe cover	BWP	I (exempt)
21 CFR 878.4040	Operating-room shoes	FXW	I (exempt)
21 CFR 878.4040	Surgical apparel accessory	LYU	I (exempt)
21 CFR 878.4040	Non-surgical isolation gown	OEA	I (exempt)
21 CFR 878.4040	Operating-room shoe cover	FXP	I (exempt)
21 CFR 878.4040	Surgical helmet	FXZ	I (exempt)
21 CFR 878.4040	Surgical cap	FYF	I (exempt)

Waiver of Certain FDA Requirements

The following requirements for authorized gowns and other apparel are waived:

· applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized gowns and other apparel used in accordance with this EUA; and

· labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that authorized gowns and other apparel must include the labeling elements specified in the Conditions of Authorization (Section IV).

·Compliance with 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 **(Registration and Listing) are not required under this EUA.**

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CHINA EXPORT CONTROL OF PPEs

China is now enforcing stringent new export requirements on medical products being used to respond to the COVID-19 pandemic. Specifically, exports of the following products 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.

- COVID-19 test kits
- ventilators
- medical protective clothing
- medical protective masks
- medical surgical masks
- one-time use medical masks
- infrared thermometers

Previously exporters of such goods were only required to work with the foreign importer to make sure the product was compliant with the relevant requirements of the importing country, and there was no special requirement for export certification.

Effective immediately licensed manufacturers that export medical products on their own must have licenses ready and have their products tested to be eligible for export. Trading companies must have the manufacturer's business license and NMPA certificate as well as a certification from an authorized testing lab.

As there is a growing need for these medical products all over the world, there is likely to be an increase in the number of licensed manufacturers. Attached are current lists of licensed manufacturers and authorized testing labs.

While these new requirements apply only to the listed products for medical use, many China exporters say they are being asked by local Chinese customs officials to furnish all three documents for products that are similar but are only for personal or industrial use. It is possible these officials are misinterpreting the new requirement, so exporters will need to communicate with them to solve any such problems.

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U.S EXPORT CONTROL OF PPEs

CSMS #42439611 - CBP processes for the Federal Emergency Management Agency (FEMA) Exemptions from the Temporary Final Rule (TFR) Published in the Federal Register on April 10, 2020.

On April 21, 2020, the Federal Emergency Management Agency (FEMA) published in the Federal Register a notice of exemptions from the allocation order issued through a Temporary Final Rule (TFR) published on April 10, 2020. The intent of the allocation order is to ensure that materials subject to the Presidential Memorandum (PM) regarding allocating certain scarce or threatened personal protective equipment (PPE) materials (covered materials) remain in the United States for use in responding to the spread of COVID-19, and to prevent domestic brokers, distributors, and other intermediaries from diverting such covered materials overseas.

Covered materials are defined in the FRN which can be found at https://www.federalregister.gov/documents/2020/04/21/2020-08542/prioritization-and-allocation-of-certain-scarce-or-threatened-health-and-medical-resources-for and may be summarized as:

- N-95 Filtering Facepiece Respirators,
- Other Filtering Facepiece Respirators (N99, N100, R95, R99, R100, or P95, P99, P100),
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- PPE surgical masks,
- PPE gloves or surgical gloves,

Pursuant to the allocation order, FEMA may review shipments of covered materials and, subject to certain exemptions, determine whether to (1) purchase some or all of the shipment through a Defense Protection Act priority-rated order, (2) return some or all of the shipment for domestic use, or (3) allow some or all of the export to proceed.

Covered materials that are being exported and that fall into one or more of the exemptions described below may proceed immediately for export as scheduled.

1. *Shipments to U.S. Commonwealths and Territories, Including Guam, American Samoa, Puerto Rico, U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Including Minor Outlying Islands).*
2. *Exports of covered materials by non-profit or non-governmental organizations that are solely for donation to foreign charities or governments for free distribution (not sale) at their destination(s).*
3. *Intracompany transfers of covered materials by U.S. companies from domestic facilities to company-owned or affiliated foreign facilities.*

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4. *Shipments of covered materials that are exported solely for assembly in medical kits and diagnostic testing kits destined for U.S. sale and delivery.*
5. *Sealed, Sterile Medical Kits Where Only a Portion of the Kit is Made Up of One or More covered materials That Cannot be Easily Removed Without Damaging the Kits.*
6. *Declared diplomatic shipments from foreign embassies and consulates to their home countries. These may be shipped via intermediaries (logistics providers) but are shipped from and consigned to foreign governments.*
7. *Shipments to Overseas U.S. Military Addresses, Foreign Service Posts (e.g. Diplomatic Post Offices), and Embassies.*
8. *In-Transit Merchandise: Shipments in Transit through the United States with a Foreign Shipper and Consignee, Including Shipments Temporarily Entered into a Warehouse or Temporarily Admitted to a Foreign Trade Zone.*
9. *Shipments for Which the Final Destination is Canada or Mexico.*
10. *Shipments by or on behalf of the U.S. Federal Government, including its Military.*

In addition, the export of covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020 are exempt, so long as at least 80 percent of such manufacturer's domestic production of such covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. FEMA and CBP are working to establish a process to identity the manufactures that qualify for this exemption.

In order to qualify for exemptions 2, 3, 4, 8, and 9, FEMA requires a letter of attestation, submitted via the document imaging system (DIS). For these exemptions, the exporter, shipper or their agents should present the letter via DIS, on company letterhead, signed by a responsible company official, including:

- a description of which exemption(s) the exporter is claiming;
- details regarding the shipment that are sufficient for the CBP and FEMA officials to determine whether the shipment falls under the claimed exemption(s), including the required information identified in the Federal Register notice published on April 21, 2020;
- a statement that the provided information is true and accurate to the best of the exporter's knowledge, and that the exporter is aware that false information is subject to prosecution under the DPA, as outlined in the allocation order.

Regarding exemption 9, the letter of attestation must state that the covered materials are for use in Canada/Mexico, and will not be transshipped through those countries and for exemption 8 it largely applies to goods temporarily entered into a bonded warehouse or Foreign Trade Zone with the intent to leave the US.

In order to avoid detention of shipments, letters should be uploaded in DIS at the same time as the Electronic Export Information (EEI) is transmitted in the Automated Export System (AES).

When submitting to DIS, filers have the following options to transmit:

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1. Electronically through secure web services, file transfer protocol, or messaging queue.
2. By Email to docs@cbp.dhs.gov

Successful submissions will receive an automated 'submission status email' indicating Success or Failure. Technical guidelines for electronic or e-mail submission are available at www.cbp.gov/ace-dis

For questions about the process or specific shipment issues contact utilize the COVID—19 Exports Intake at https://imports.cbp.gov/s/. Select the Export Cargo Hold/Facilitation Assistance button.

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Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection

Not required to transmit Registration, Listing or 510(k) during the Covid-19 Public Health Emergency.

To ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks (not including respirators) that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency:

- Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,
- Registration and Listing requirements in 21 CFR 807,
- Quality System Regulation requirements in 21 CFR 820,
- reports or corrections and removals in 21 CFR Part 806, and
- Unique Device Identification requirements in 21 CFR Part 830.

ACE Transmission Requirements for this type of face mask:

Program Code: DEV

Processing Code: NED

Intended Use Code: 081.006 Enforcement Discretion

Product Code: 80Q--KR Use the Product Classification and Product Code Builder

Please see FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) for a full list of ACE transmission requirements, including mandatory/conditional/optional AofCs.

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Surgical Masks Intended to Provide Liquid Barrier Protection

Not required to submit a 510(k) during the Covid-19 Public Health Emergency, but registration and listing are still required.

Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are tested for flammability and biocompatibility. FDA does not intend to object where, for the duration of the declared public health emergency, surgical masks are distributed and used without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, and the surgical masks do not create an undue risk in light of the public health emergency. The product meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F18627Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

- The product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);
- The product includes labeling that accurately describes the product as a surgical mask and includes a list of the body contacting materials (which does not include any drugs or biologics); and
- The product is not intended for any use that would create an undue risk, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

ACE Transmission Requirements for surgical masks:

Program Code: DEV

Processing Code: NED

Intended Use Code: 081.001 Standard Import of a foreign manufactured device

081.006 Enforcement Discretion

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Product Code: 80F--XX Use the Product Classification and Product Code Builder

Please see FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) for a full list of ACE transmission requirements, including mandatory/conditional/optional AofCs.

NIOSH Approved Filtering Facepiece Respirators (including N95s) under EUA

See Emergency Use Authorization letter. NIOSH approved respirators authorized under this EUA are listed in NIOSH CEL for non-powered air purifying respirators with particulate protection and the NIOSH CEL for PAPRs with particulate protection

Under this re-issued letter, manufacturers do **not** need to submit attestation to FDA in order to request authorization of additional NIOSH-approved respirators and strategic stockpilers do **not** need to submit request to FDA to request authorization of additional NIOSH-approved respirators.

Note to Importers

- All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

- No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.

- Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

- Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.

ACE Transmission Requirements for NIOSH Approved FFRs including N95s under EUA:

Program Code: DEV

Processing Code: NED

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Intended Use Code: 940.000 if the product is listed on CDC/NIOSH website

081.001 if not listed on CDC or NIOSH website

Product Code: 80N—ZJ or 80O—RW (with antimicrobial or antiviral agent)

Use the Product Classification and Product Code Builder

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 CDC website

081.001 if not listed on CDC website

Product Code: 80N—ZJ

Use the Product Classification and Product Code Builder

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Non-NIOSH Filtering Facepiece Respirators 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.

Non-NIOSH Filtering Facepiece Respirators under EUA that are intended for medical use must be listed on Exhibit 1 and have an Emergency Use Authorization to be imported for medical use. See Emergency Use Authorization Letter.

If you wish to import masks identified in the EUA letter and they are not listed in Exhibit 1, send an email notification to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the following information:

- Specify the manufacturer, model number(s), marketing authorization/certificate from another regulatory authority or conformity assessment body acting on their behalf (including the authorization number (if any)), certificate of conformity (if available), applicable performance standards that their product meets, and any applicable guidance documents.
- An estimate of the number of respirators you are planning to import during the public health emergency,
- A copy of the product labeling. Respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

Please note: Canada is not listed because it allows self-declaration to NIOSH or equivalent standards. If importing respirators from Canada, follow the instructions for Filtering Facepiece Respirators (including N95s) under EUA.
For any face mask or filtering facepiece respirator (including N95 respirators) issued an EUA, FDA will include appropriate conditions of authorization in accordance with section 564 of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, we will likely include the following conditions:

- Appropriate conditions designed to ensure that health care professionals administering the device are informed— that FDA has authorized the emergency use of the device; of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and of the alternatives to the device that are available, and of their benefits and risks.
- Appropriate conditions designed to ensure that individuals to whom the device is administered are informed— that FDA has authorized the emergency use of the device; of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and of the option to accept or refuse administration

of the device, of the consequence, if any, of refusing administration of the device, and of the alternatives to the device that are available and of their benefits and risks.

- Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the device. FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.

For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.

ACE Transmission Requirements for Non-NIOSH FFRs under EUA:

Program Code: DEV

Processing Code: NED

Intended Use Code: 940.000 if the product is listed on CDC website or Exhibit 1 if Non-NIOSH EUA

081.001 if not listed on CDC or NIOSH website

Product Code: 80N—ZJ or 80O—RW (with antimicrobial or antiviral agent)

Use the Product Classification and Product Code Builder

Please see FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) for a full list of ACE transmission requirements, including mandatory/conditional/optional AofCs.

Please refer to the following updated policy documents:

- Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency
- Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency
- FAQs on Diagnostic Testing for SARS-CoV-2
- Emergency Use Authorizations

Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China

FDA has re-issued EUA for non-NIOSH approved face masks manufactured in China because certain Chinese manufacturers were not meeting the quality criterion under NIOSH. As such, only

manufacturers listed in Appendix A are allowed to market respirators to healthcare professionals for medical purposes.

More information can be found ono how to be added to this EUA, and other questions can be answered at:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic

Can I import respirators to the US if the standards or approval mechanism from my country is not listed as criteria for eligibility under this Emergency Use Authorization (EUA)?

Respirator manufacturers whose countries' standards or approval mechanism are not included under this EUA should submit a separate EUA request if they would like to import their product into the US for use in healthcare settings. General background on EUAs can be found here. Requests for this particular EUA should be made to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the text "Non-NIOSH-Approved Respirator" in the subject line and include:

A. General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any) in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).
B. A copy of the product labeling.
C. Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available).
D. Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes or an equivalent quality system and the manufacturer or importer has documentation of such.
E. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate

ADDITIONALLY, THE FOLLOWING ARTICLES ARE **NOT SUBJECT TO CHINA TARIFFS** (CSMS #42049352):

1) **Bowls of molded plastics**, with clips for retaining guide wires during surgical procedures (described in statistical reporting number 3926.90.9990)

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2) Disposable graduated medicine dispensing **cups of plastics** (described in statistical reporting number 3926.90.9990)

3) **Pads of foam plastics**, with hook and loop fastener straps, integrated arm protectors, and accessory headrest, body straps, lift sheets, hand grips and face masks, of a kind used for positioning patients during medical procedures (described in statistical reporting number 3926.90.9990)

4) Single-use **sterile drapes** and covers of plastics, of a kind used to protect the sterile field in surgical operating rooms (described in statistical reporting number 3926.90.9990)

5) **Sterile decanters** of polystyrene plastics, each of a kind used to transfer aseptic fluids or medication to and from sterile bags, vials or glass containers (described in statistical reporting number 3926.90.9990)

6) **Cold packs** consisting of a single-use, instant, endothermic chemical reaction cold pack combined with a textile exterior lining (described in statistical reporting number 6307.90.9889)

7) **Disposable shoe and boot covers** of man-made fiber fabrics (described in statistical reporting number 6307.90.9889)

8) **Eye compresses**, each consisting of a fabric cover filled with silica or gel beads, with or without a hook-and-loop fastener strap (described in statistical reporting number 6307.90.9889)

9) **Face mask**s, single-use, of textile fabrics (described in statistical reporting number 6307.90.9889)

10) **Gel pads** of textile materials, each with removable fabric sleeves, in the shape of hearts, circles or quadrants (described in statistical reporting number 6307.90.9889)

11) **Hot packs** of textile material, single-use (exothermic chemical reaction) (described in statistical reporting number 6307.90.9889)

12) **Laparotomy sponges** of cotton (described in statistical reporting number 6307.90.9889)

13) **Patient restraint** or safety straps of textile materials, with hook-and-loop or ladder lock fasteners (described in statistical reporting number 6307.90.9889)

14) Single-use **blood pressure cuff sleeves** of textile materials (described in statistical reporting number 6307.90.9889)

15) Single-use **medical masks** of textile material (described in statistical reporting number 6307.90.9889)

16) Single-use **stethoscope covers** (described in statistical reporting number 6307.90.9889)

17) **Woven gauze** sponges of cotton in square or rectangular sizes (described in statistical reporting number 6307.90.9889)

18) **Electromechanical shoe cover dispenser**, of steel (described in statistical reporting number 8479.89.6500)

19) **Protective articles** (described in statistical reporting number 9004.90.0000)

These include Spectacles, goggles and the like, corrective, **protective** or other:

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VENTILATORS:

If the manufacturer is registered with the FDA, then we would need:

Device Foreign Manufacturer #

Device Foreign Exporter #

Device Listing #

*If they are **not** registered with the FDA*, then we need to request an Emergency Use Authorization (EUA) so they can be added on the approved EUA list (appendix B attached). Once the manufacturer is approved for EUA list, they would not need to provide the above FDA numbers.

In order to be placed on the EUA list, the manufacturer needs to provide information requested in Appendix A (attached), and section II /IV of the attached DHHS Letter. We can then submit the request to CDRH-COVID19-Ventilators@fda.hhs.gov

The following manufacturers of ventilators are allowed to export their products under the EUA:

- Beijing Aeonmed Co., Ltd
- Shenzhen Mindray Biomedical Electronics
- Vyaire Medical, Inc.
- Resmed

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THERMOMETERS FOR MEDICAL USE:

Contact and Non-contact thermometers are FDA regulated. As such they require

1. submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,
2. Reports of Corrections and Removals requirements in 21 CFR 806,
3. Registration and Listing requirements in 21 CFR Part 807, and
4. Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20

To clear customs we would need:

1. Foreign Device Manufacturer #
2. Foreign Device Exporter #
3. Device Listing Number#

However, during the COVID-19 emergency, FDA has FDA does not intend to object to the distribution and use of clinical electronic thermometers that are not currently 510(k) cleared without compliance with the above mentioned regulatory requirements where such devices do not create an undue risk in light of the public health emergency.

Nonetheless, certain requirement need to be met during COVID-19(listed below), and FDA is willing to work with importers on this. Inquiries about thermometers need to be directed to: CDRH-COVID19-Thermometers@fda.hhs.gov

COVID-19 Thermometer Regulatory Requirements:

1. The device is manufactured consistent with 21 CFR Part 820, ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes, or equivalent quality system approach
2. The device has marketing authorization in another regulatory jurisdiction (European CE Mark, Australian Register of Therapeutic Goods Certificate of Inclusion, Health Canada License, **or** Ninsho certification in Japan), or the performance of the device conforms to the standards listed in attached guidance doc (page 3).
3. The device labeling includes a clear description of the available data on the device's indications or functions including:
   a. Device performance;
   b. Method of determining temperature;
   c. Potential risks; and

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d. Cleaning and reprocessing instructions.

4. The device labeling includes a clear identification that the device is not FDA approved or cleared.

FDA Enforcement Policy for thermometers during COVID-19 can be found at the link below:

https://www.fda.gov/media/136698/download

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FACE SHIELDS FOR HEALTHCARE PROFESSIONALS AND HOSPITAL USE:

Face shields for use by HCP as PPE are authorized under this EUA when they are intended for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection and meet the following requirements:

A. The product is labeled accurately to describe the product as a face shield for medical purposes and includes a list of the body contacting materials (which does not include any drugs or biologics);

B. The product is not integrated with any other article of PPE such as a face mask, but rather is for use as a standalone face shield.

C. The product includes labeling that describes the product as intended for either a singleuser, single use, or for multiple uses by the same user, and includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable.

D. The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);

E. The product is not intended for any use that would create an undue risk in light of the public health emergency; for example, the labeling does not state that use of the authorized face shield alone will prevent infection from microbes or viruses, or that it is effective against radiation protection. As indicated in Section I, face shields authorized by this EUA may be effective at preventing HCP exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19. All manufacturers are reminded that they must comply with all Conditions of Authorization, including those relating to advertising and promotion in Section IV of this letter.

Waiver of Certain FDA Requirements:

- applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized face shields used in accordance with this EUA; and
- labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that face shields must include the labeling elements specified in the Conditions of Authorization (Section IV).

More info on this EUA can be found at:

https://www.fda.gov/media/136842/download