This guide is intended to steer decision makers, logisticians, purchasers, and others to available federal information resources to assist in vetting protective equipment and medical devices that are in high demand during the COVID-19 emergency. It is not intended to be exhaustive, and does not constitute legal, medical, or expert advice. Refer to links to online content for the latest information. This document was last updated April 16, 2020, version 2.0.
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**How to Assess Products—Quick Reference**

**Filtering Facepiece Respirators**
Look for [NIOSH certification](https://www.osha.gov/SLTC/ets/NIOSH.html), [FDA clearance](https://www.fda.gov), if also used as a surgical mask, and, if not NIOSH-approved, check the [FDA Emergency Use Authorization list](https://www.fda.gov).

**Face masks**
Also known as surgical masks, look for [FDA clearance](https://www.fda.gov).

**Gowns and coveralls**
Look for product labeling for ANSI/AAMI PB70
Level 1–2 [gowns only] or describing uses consistent with the Level 1–2 risk levels described on p. 9, e.g., “fluid/water resistant.”

**Face shields**
Products that cover the front and sides of face and labeled for medical use.
Medical Devices (General)
For medical devices in general, to determine if the device is cleared (class II) or approved (class III):

**Class I Examples**
(registration only)
- Isolation gowns **OEA**
- Bandage, adhesive **KGX**

**Class II Examples**
- Surgical gowns **FYA**
- Surgical masks **FXX**
- Surgical respirators **MSH**

**Class III Examples**
- Defibrillators **MKJ**
- Implanted devices **LWP**
- Ventilators **CBK**

1. Is the medical device firm registered with the FDA?

   **YES**
   2. Is the specific product listed with the medical device firm?

      **YES**
      - The product is cleared/approved by the FDA for its use (may require other regulatory approvals, e.g., NIOSH for N95)
      **NO**
      - Go to step 3

   **NO**
   3. Has the specific product been entered and approved as Emergency Use Authorization (EUA)?

      **Listed on EUA**
      - Approved for use
      **Not Listed on EUA**
      - Not approved for use

      Consider contacting CDRH to determine if approval is underway

**FDA Establishment Registration & Device Listing Search**

**FDA Emergency Use Authorizations (for COVID-19)**

Scan the QR codes to access these websites on a smartphone or other mobile device.
Searching the FDA Establishment Registration & Device Listing
In this example, a maker of a scavenging mask is searched using the registration number they provided.

1. Is the specific product registered and listed with FDA? A firm can be registered and list specific products but if the specific product is not listed with the other ones that are, then no.

2. Using the link above, enter a trade name, owner name, or registration number:

3. Click on the Mask, Scavenging for the specific use for this specific device.
4. Click on regulation number: 868.5590

<table>
<thead>
<tr>
<th>[Code of Federal Regulations]</th>
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<tr>
<td>[Revised as of April 1, 2019]</td>
<td>[CITE: 21 CFR 868.5590]</td>
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**TITLE 21—FOOD AND DRUGS**
**CHAPTER I—FOOD AND DRUG ADMINISTRATION**
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**SUBCHAPTER H—MEDICAL DEVICES**

PART 868 — ANESTHESIOLOGY DEVICES
Subpart F—Therapeutic Devices

Sec. 868.5590 Scavenging mask.

(a) Identification. A scavenging mask is a device positioned over a patient’s nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 868.9.


5. From the regulation, a scavenging mask is used to deliver anesthetic through the nose. It is not a surgical respirator or mask.

This fictitious manufacturer is registered to market a scavenging mask but is not cleared to market surgical masks or surgical respirators.

There are reports of KN95 masks that are not up to specification and are not listed, and some firms trying to say “we are registered” as a cover statement.

1. Again, if registered, does the specific product show up? Ask sales representative for evidence and proof.
2. If no, then is the specific product registered with EUA on the website?

If yes, it can be ordered and used. If no, it may be advisable to check directly with the FDA Center for Devices and Radiological Health (CDRH) to determine if the product is working its way through the EUA approval process.
Filtering Facepiece Respirators (FFRs)
Commonly referred to as an “N95” using a US standard as the shorthand name, an FFR is a tight-fitting mask that filters out particulate matter (95% in the case of an N95) as small as 0.3 μ. In the US, an FFR is approved by CDC’s National Institute for Occupational Safety and Health (NIOSH). An FFR may also be cleared by FDA for use as a surgical mask—protecting the wearer and the patient.

Not all NIOSH-approved respirators are also FDA-cleared for use as a surgical mask. Masks approved by NIOSH for use in construction, for example, may not be suitable for use in medical settings. Two Emergency Use Authorizations allow for the use of specially-approved FFRs that received regulatory approval from China and selected other countries.

List of FDA-cleared NIOSH FFRs for Use as Surgical Respirators
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3surgicaln95.html

List of FFRs approved under Emergency Use Authorization (EUA)
- International (March 28, 2020 EUA Exhibit 1) https://www.fda.gov/media/136731/download
- Chinese KN95 (April 3, 2020 EUA Appendix A) https://www.fda.gov/media/136663/download
Contacting CDRH
FDA’s Center for Devices and Radiological Health (CDRH) has a special resource mailbox for communication related to EUA approvals of N95-equivalent FFRs: CDRH-COVID19-SurgicalMasks@fda.hhs.gov

Filtering Facepiece Respirator (FFR) Labels

**Figure 1** Sample of markings required (and some optional) on a NIOSH-approved filtering facepiece respirator (CDC NIOSH).

**Practical Considerations**
A wearer of an FFR must be fit tested for each model of FFR used. Some FFRs come in different sizes and health care providers include many personnel requiring small size masks for adequate face seal.

**Additional Resources:**
- List of NIOSH-approved N95 FFRs [https://www.cdc.gov/niosh/nptl/topics/respirators/disp_part/n95list1.html](https://www.cdc.gov/niosh/nptl/topics/respirators/disp_part/n95list1.html)
Face Masks
A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer meant to help block large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching your mouth and nose. Surgical masks may also help reduce exposure of your saliva and respiratory secretions to others. Surgical masks do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the face mask and your face. (FDA)

Surgical masks are regulated under 21 CFR 878.4040 and should be cleared by the FDA.

Resources
- FDA N95 Respirators and Surgical Masks (Face Masks) https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s2
- Comparing Surgical Masks and Surgical N95 Respirators https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s4
Gowns and Coveralls

Figure 2 Examples of a typical coverall and an isolation gown (CDC).

Gowns or isolation gowns and coveralls protect the wearer from the spread of infection or illness if the wearer comes in contact with potentially infectious liquid and solid material. The FDA recognizes the consensus standard American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70, “Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities,” separating gowns into four levels:

**ANSI/AAMI PB70 Risk Levels**
- **Level 1:** Minimal risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit
- **Level 2:** Low risk, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab
- **Level 3:** Moderate risk, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases
- **Level 4:** High risk, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne)

Surgical gowns are at levels 3–4 and require FDA clearance. For Level 1–2 personal protective equipment, look for product labeling that describes an intended use with the desired level of protection based on the above risk levels. According to FDA guidance, product claims such as “protective apparel,” “effective barrier,” “fluid-resistant,” “water resistant,” or “splash resistant” are consistent with level 1–2. CDC recommends (p. 13) cuffed sleeves.

**Practical Considerations**
Coveralls provide protection but are more time consuming for donning and doffing. Therefore, gowns are sometimes preferred in hospitals since they allow wearers to quickly doff the protective garment before going to another patient.

**Resources:**
- Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids [https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/default.html](https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/default.html)
Face Shields
An April 13, 2020, Emergency Use Authorization provides broad authority for face shields. Products used by healthcare providers as personal protection equipment are authorized under the EUA for use in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection if they meet the following requirements:

1. **Labeled for Medical Use**
   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);

2. **Not Integrated with Other PPE**
   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.

3. **Is Single Use or Includes Cleaning/Disinfection Instructions**
   The product includes labeling that describes the product as intended for either a single-user, single use, or for multiple uses by the same user, and includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable.

4. **Not Flammable**
   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);

5. **No Exotic Claims e.g., Anti-Viral, Radiation Shielding, etc.**
   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.

**Resources:**
- April 13, 2020, Emergency Use Authorization for Face Shields
  [https://www.fda.gov/media/136842/download](https://www.fda.gov/media/136842/download)
References
US FDA. Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators. 3 Apr 2020
https://www.fda.gov/media/136664/download


https://crsreports.congress.gov/product/pdf/IF/IF11488

US DHHS CDC NIOSH
https://www.cdc.gov/niosh/emres/2019_ncov.html
Respirator Information
Approved N95 respirators
https://www.cdc.gov/niosh/nptl/topics/respirators/disp_part/n95list1-a.html

US FDA. Frequently Asked Questions about Masks and Gowns

US FDA. Medical Devices Page (including PPE Issues/Questions and 24X7 Hotline)

US FDA. Division of Industry and Consumer Education. Contact Information.
https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice

Specific POC contact for questions about masks: CDRH-COVID19-SurgicalMasks@fda.hhs.gov
Emergency Use Authorization (EUA)

Typically, the EUA process is what firms should follow if they are looking to assist with the COVID-19 response.


CDRH has issued immediately in effect guidance documents for these EUA products, as well as some other products.

The list of current guidance documents is located here:


Firms should review the guidance for the specific product they manufacture, or are interested in manufacturing, and once they have all the relevant info, they should send to CDRH through the appropriate email (which is usually listed in the associated guidance document).

Here is a summary of some emails, although there may be other emails listed in additional guidance documents:

- COVID19FDAIMPORTINQUIRIES@fda.hhs.gov For import questions
- CDRH-COVID19-Ventilators@fda.hhs.gov For ventilator questions
- CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov For those who meet the definition of an Emergency Use Authorization (EUA) and are ready to send information. This email is NOT for diagnostic kits.
- CDRH-EUA-Templates@fda.hhs.gov For those who are wanting to submit an EUA for a diagnostic test (i.e. an IVD)
- CDRH-COVID19-SurgicalMasks@fda.hhs.gov For EUA information related to face masks and respirators

FAQs on Shortages of Surgical Masks and Gowns


See question 3 for details on how/when to contact deviceshortages@fda.hhs.gov for FDA engagement on considering increasing availability of surgical masks/gowns to the US market.