



COVID-19 Supply Chain Response

A collaborative partnership with the U.S. Food & Drug Administration, the National Institute of Allergy and Infectious Diseases, the Veterans Healthcare Administration, and America Makes

Surgical Face Masks for Clinical Use: Checklist for Manufacturers

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|--------------------------|--------------------------------------|--|
| <input type="checkbox"/> | Labeling* | Does the device have the appropriate labeling included? |
| <input type="checkbox"/> | Product Tracking | Have the quantity and description of the devices being distributed to each customer been documented appropriately? Has a method been offered for receiving, recording, and tracking potential issues with devices? |
| <input type="checkbox"/> | Good Manufacturing Practices (GMP)** | Was the device produced according to an established quality system to help ensure that the device consistently meets applicable requirements and specifications as described by the FDA? |
| <input type="checkbox"/> | Registration and Listing*** | Are you registered with the FDA for the devices you are producing/distributing? |
| <input type="checkbox"/> | Unadulterated Product | Has anything been done to alter the method of manufacture prior to final distribution to the user? It is not recommended that any changes be made to the practices provided for devices downloaded from the clinically reviewed category on NIH 3D print exchange. If changes have been made, it is the manufacturer's responsibility to understand the consequences of these alterations to the product method of manufacture on device safety and effectiveness. |
| <input type="checkbox"/> | Adverse Event Tracking | Manufacturers must report to the FDA upon discovery of an adverse event where the device may have caused or contributed to a death or serious injury. Are you tracking such matters appropriately for your devices? |
| <input type="checkbox"/> | Instructions for Use | Have the instructions for use been included with the device(s)? Does this contain all of the important details, including but not limited to: intended use, how to wear/use, store, assemble, clean, and dispose of the product and any issues or risks known which can affect the user? We suggest including information regarding materials, warnings, performance testing, adverse reactions, and a disclaimer. |

Note: This document is provided as a guide to help inform the production process of personal protective equipment and medical devices during the COVID-19 public health emergency. The FDA, NIH, VA, and America Makes cannot ensure the quality, safety, and efficacy of these designs when manufactured without proper quality controls and processes.



Surgical Face Masks for Clinical Use: Checklist for Manufacturers

This checklist applies to face masks that are designated as surgical masks, most notably, those in the “Clinical Use” category in the NIH 3D Print Exchange [collection for COVID-19 PPE](#). A surgical mask covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests. Please refer to the NIH site for additional information about face masks and materials safety.

The FDA has granted Emergency Use Authorization (EUA) waiving some of the requirements for face masks for the duration of the COVID-19 public health emergency. Manufacturers, users, and other stakeholders should review the [FDA’s statement on face masks](#) and refer to their announcements on [EUAs for PPE and medical devices](#).

- ***Labeling** includes the name and place of the manufacturer or distributor, the name of the device and its intended purpose, its materials, and whether or not a device is reusable or for single-use only.
- ****Good Manufacturing Practices (GMPs)** refers to the quality systems for FDA-regulated products (food, drugs, biologics, and devices) that ensure products consistently meet applicable requirements and specifications.
- *****Registration and Listing:** the FDA requires that businesses producing and distributing medical devices in the U.S. register annually with the FDA.

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