

3D PRINTING: COVID-19 General Manufacturing Considerations

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Some things you need to understand and consider before printing and distributing a medical device

For up-to-date information and resources, visit:
www.AmericaMakes.us/covid-19

Before you start, ask yourself how you feel.

If you believe you are ill, or could potentially be ill, or may have recently been ill, please do not produce anything, get plenty of rest, and concentrate on getting and staying well.

Are you confident you can print the design you downloaded?

If, for any reason, you are unsure about how to do what is necessary or think you may be doing something wrong, stop. It is important you research your concerns and address them. This is not the time to take chances.

Don't make changes to the designs.

We recommend manufacturers use the design as presented and strictly adhere to the recommended practices outlined in the data package from the NIH 3D Print Exchange prior to printing, assembling, and shipping a part.

Understand the risks.

The risk and liability of printing and distributing a medical device rests with the manufacturer who produces and distributes that device to a user.

Understand "Community Use."

If you are making a device that will be used in a non-medical setting and are making no medical claims, it is considered a "community use" device and not a medical device. FDA jurisdiction is limited to only medical devices.

Understand GMP.

GMP stands for good manufacturing practice. GMP is part of a manufacturer's quality system and helps ensure their products consistently meet applicable requirements and specifications. Typically, a manufacturer following GMP means they maintain a relevant certification for all respective quality systems utilized in the production of devices.

You can still make products if you don't have GMP.

Face shields, community use face masks, mask tension release bands, and hands free door opening devices can be manufactured without GMP.

These parts are not FDA or NIH approved.

They are not endorsed in any manner.

The designs available on the NIH 3D Print Exchange have undergone review in a clinical setting and the FDA has been given access to the test protocol. Devices listed as "Clinically Reviewed" fall with existing emergency use authorization (EUA) guidance or are not medical devices.

You must provide instructions for use (IFU).

The manufacturer is responsible to provide the users with information regarding the intended use of the product; how to wear or use the item; how to store, assemble, clean, and dispose of the product; along with any issues or risks known which could affect the user. We suggest including information regarding materials, warnings, performance testing, adverse reactions, and any and all disclaimers.

You are responsible for tracking.

The manufacturer must track how many of each device is distributed to each customer. If there are any reported issues with the product, the manufacturer must offer a method for those issues to be received from the customer, recorded, and tracked.

You are responsible for labeling.

Medical devices sold in the United States must be labeled — from manufacturing through distribution to patient use. A labeler is any person who causes a label to be applied to a device, or who causes the label of a device to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler is the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.

You are expected to comply with what happens after the pandemic.

If you are making these devices and the FDA issues an order to stop or informs the public the EUAs have ceased, you must immediately stop production. This is the manufacturer's responsibility.