America Makes

Driven by... NCDMM

3D PRINTING: COVID-19 Regulatory and Performance Considerations

The information below is provided to give manufacturers regulatory and product performance considerations related to producing clinically reviewed designs.

RELEASE DATE: March 31, 2021

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

Manufacturing Regulatory Considerations

Description	Face Shield	Community Use Face Mask	Surgical / Clinical Use Face Mask [1]	Mask Tension Release Bands	Personal Assistance Device	Nasopharyngeal Swabs
IFU – Instructions for Use Manufacturers are responsible for telling the user the intended use, how to wear/use the device, storage, assembly, cleansing, and disposal information. Moreover, information on materials, warnings, performance testing, adverse reactions, and a disclaimer should be included. General Device Labeling Requirements	✓	✓	✓	✓	✓	✓
Labeling Medical devices sold in the US, from manufacturing through distribution to a patient, must be labeled. Device Labeling UDI System Link	✓		✓			✓
Product Tracking Device manufacturers must track how many devices are distributed to each customer and offer a method for receiving, recording, and tracking potential issues with devices. Medical device tracking	✓		✓			✓
GMP – Good Manufacturing Practice Manufacturers must establish and follow quality systems to help ensure their products consistently meet applicable requirements and specifications. Typically, a manufacturer following good manufacturing practice (GMP) means they maintain a relevant certification for all respective quality systems utilized in the production of devices. QS Regulation and GMP Overview of Device Regulation						✓
Unadulterated Product 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.	✓		✓			✓
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. As of 2018, certain manufacturers may be able to submit voluntary summary reports of adverse events to the FDA. How to Report Medical Device Problems Mandatory Reporting Requirements	✓		✓			✓
Registration and Listing Owners or operators of places of business (or establishments/facilities) involved in production and distribution of medical devices intended for use in the US must register annually with the FDA through a process known as establishment registration. Device Registration and Listing						✓
FDA Resources, Guidance and EUA Links. Face Mask FDA Online Resource	Face Shield EUA	FDA Guidance May 2020	FDA Guidance May 2020			FAQ on Testing for SARS-CoV-2

Much of the provided information is in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services

[1] If you are making a Surgical / Clinical Use Face Mask for community use, regulatory considerations for community use face mask apply

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Minimum Performance Considerations

Description	Product Type: Face Shield	Community Use Face Mask	Surgical / Clinical Use Face Mask [1]	Mask Tension Release Bands	Personal Assistance Device	Nasopharyngeal Swabs
Chemical Compatibility Chemical characterization of devices should be conducted within the framework of a risk management process to understand what interactions and components may alter the physicochemical characteristics of the device. Use of ISO 10993-1 – Biological Evaluation	✓		✓	✓	✓	✓
Bio-compatibility Risk assessment of the device should consider chemical toxicity of the materials, the processing method, and manufacturing methods in relation to any unacceptable biological response to the device. Exposure duration of the device should be considered in evaluating biological impacts on users. *Standard: ISO 10993*		✓	✓			✓
Flammability Proper flammability standards should be adhered to based on the class of device being manufactured. For surgical masks intended for use in the operating room, Class 1 and Class 2 flammability materials are recommended by FDA. *Standard: ASTM F2100-19* Surgical Mask Guidance			✓			
Liquid Barrier The fluid resistance is the ability of the mask's material to demonstrate a liquid barrier and resist penetration of blood and bodily fluids. FDA recommends using ASTM F 1862 for surgical masks. *Standards: ASTM F1862-17; ASTM F2100-19* Surgical Mask Guidance			✓			
Face Seal Fit Face seal fit can be evaluated with a fit test, either qualitative or quantitative according to OSHA guidelines. A fit factor can also be determined as an estimated ratio of concentration of a substance in the ambient air to its concentration in the respirator when worn. *Standard: 29CFR 1910.134 App A* OSHA-Accepted Fit Test Protocols; Respiratory PPE Definitions		Loose	Loose			
Splash Resistance Splash resistance refers to protection of the facial area and associated mucous membranes from splashes, sprays, and spatters of bodily fluids. Face Shields for Infection Control	✓					
Offgassing Offgassing, or outgassing, refers to the release of volatile compounds as a gas from the materials of the device. Outgassing Wiki		✓	✓			
Cleanliness A method of cleaning the device should be established to mitigate the presence of foreign debris or contaminants which can affect testing validity or patient safety. *Standards: ASTM F3127-16* FDA Validation of Cleaning Processes						✓
Compatible Sterilization Methods Compatible sterilization methods are developing and are defined as processes to clean and disinfect soiled medical devices to render them safe for handling and to the extent necessary for subsequent processing. Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency			✓			✓

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The information below is provided to give a sampling of designs that are available to be manufactured. Manufacturers should thoroughly read and understand the Regulatory and Performance Considerations.

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www.AmericaMakes.us/amcpr

Available Designs

NIH 3D Print Exchange Design IDs

To see an up-to-date listing of downloadable design files,
visit: the NIH 3D Print Exchange

Product Type					
Face Shield	Community Use Face Mask	Surgical / Clinical Use Face Mask [1]	Mask Tension Release Bands	Personal Assistance Device	Nasopha-ryngeal Swabs
3DPX-013306	3DPX-013319	3DPX-013429	3DPX-013410	3DPX-013380	
3DPX-013309	3DPX-013321	3DPX-013836	3DPX-013440	3DPX-013564	
3DPX-013314	3DPX-013354		3DPX-013574	3DPX-013615	
3DPX-013359	3DPX-013384		3DPX-013675	3DPX-013752	
3DPX-013374	3DPX-013477			3DPX-013793	
3DPX-013375	3DPX-013505			3DPX-013860	
3DPX-013403	3DPX-013512			3DPX-013967	
3DPX-013406	3DPX-013519			3DPX-014017	
3DPX-013409	3DPX-013545			3DPX-014103	
3DPX-013421	3DPX-013603			3DPX-014147	
3DPX-013444	3DPX-013607			3DPX-014188	
3DPX-013456	3DPX-013661			3DPX-014357	
3DPX-013532	3DPX-013674			3DPX-014417	
3DPX-013616	3DPX-013677				
3DPX-013830	3DPX-013690				
3DPX-013883	3DPX-013693				
3DPX-013884	3DPX-013807				
3DPX-013887	3DPX-013885				
3DPX-013989	3DPX-013934				
	3DPX-014004				
	3DPX-014080				
	3DPX-014173				

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