Navigating Temporary Use Authorizations: Face Masks

19OCT2020

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To help reduce spread of COVID-19, the United States (US) Centers for Disease Control and Prevention (CDC) recommends wearing a mask in public settings when social distancing is difficult to maintain. To support this use, the US Food and Drug Administration (FDA) released temporary guidance under the Emergency Use Authorization (EUA) to improve supplies of masks and other products needed in the ongoing COVID-19 Public Health Emergency. Companies are wondering what this means for them and the products they are producing now and in the future after the EUA ends. For face masks used as personal protective equipment (PPE), each company must navigate FDA regulations and standards related to face masks, face shields, surgical masks and N95 respirators. This article outlines Face Masks and Surgical Masks for COVID-19 and describes FDA work to increase mask availability across the US.

Let's start with some FDA definitions.

A Face Mask or *cloth face covering* is designed to cover the nose and mouth and may be disposable or reusable. Face masks act as protective barriers to prevent splashes, sprays, large droplets, or splatter from entering the wearer's mouth and nose. They also help prevent the wearer from spreading respiratory droplets or bodily fluids like those spread in a sneeze or cough. The protective quality of face masks varies depending on type of material used to make the face mask. A Face Shield is made of plastic and is designed to protect the face including eyes, nose and mouth from fluids including respiratory droplets or bodily fluids. Face masks and face shields may be used together or separately and are intended for use by the general public and by health care professionals (HCPs) as a simple barrier. A Surgical Mask is also designed to cover the nose and mouth; however, FDA regulates surgical masks in a higher risk category (Class II, medium risk) than face mask and face shield (Class I, low risk) devices. Unfortunately, masks and shields are not *respirators* and none of them protect wearers from breathing in small airborne particles, gases, or chemicals.

Respirators protect wearers from breathing in hazardous airborne contaminants. A Filtering Facepiece Respirator (FFR) covers the nose and mouth (half-face), is non-powered, disposable and designed to purify air by removing particulates. FFRs are intended to help reduce exposure to "pathogenic biological airborne particulates." N95 Respirators must filter out 95% of airborne particulates 0.30 microns in size or larger. For comparison, most viruses are much smaller than 0.30 microns and they can be as small as 0.005 microns. Of interest here, Coronavirus is only 0.06 to 0.14 microns, so the virus can go through masks and N95 respirators. Respiratory droplets containing MANY virus particles are much larger and may be stopped, at least in part, by

mask/respirator barriers. In particular, a Surgical N95 Respirator is worn by HCPs during procedures in a healthcare setting to prevent wearers from inhaling microorganisms, particulates or splashed body fluids.

Now, let's add in some regulations.

One part of the US Code of Federal Regulations (21CFR878.4040) covers "surgical apparel" including surgical masks and N95 FFRs used in a healthcare setting. US FDA regulations specify how lower risk (Class I) surgical devices (e.g., surgical caps and shoe covers) need only "general controls" including (but not limited to) current good manufacturing practices (cGMP)(21CFR820), appropriate labeling and safety reporting. Regulations also specify low-risk devices as "exempt" from premarket notifications and special testing requirements in place for surgical masks and N95 respirators.

Normally, the FDA requires higher risk (Class II) surgical face masks and N95 respirators to use both "general" and "special controls" to ensure safety and efficacy. Special controls include an FDA premarket notification [also called a 510(k) submission] as well as specific tests to meet certain fluid barrier protection standards and flammability requirements before products can be placed in US markets. During the COVID-19 emergency, the FDA is using enforcement discretion to relax requirements. Surgical N95 respirators and N95 FFRs still require premarket notification for use to prevent disease or infection, to filter out specific viruses like coronavirus, or to include coatings or added chemicals to kill microorganisms.

The FDA groups medical devices under a product code. For example, public-use face masks fall under product code QKR, surgical masks under FXX and surgical respirators are grouped under product code MSH. The FDA lists recognized consensus standards and safety concerns for all devices in each product code group. For example, no standards are listed for **face masks** and face mask manufacturers may or may not test their products to meet voluntary, fluid barrier or filtration efficiency levels. Conversely, standards listed for **surgical respirators** describe tests for fluid penetration and filtration efficiency and **surgical masks** must comply with specific performance standards, not limited to:

- ASTM F1862 liquid barrier penetration using synthetic blood
- ASTM F2100-19 filtration efficiency and air-flow resistance requirements
- ASTM F2101-19 bacterial filtration efficacy using biological aerosol of staphylococcus aureus
- 16CFR1610 Class I or Class II textile flammability requirements
- ISO 10993 biocompatibility testing (cytotoxicity, sensitization, irritation) for user-contacting surfaces

Certain respiratory protective devices need test results showing specific filter efficiency levels (42CFR84.174 for non-powered air-purifying respirators) or requirements to ensure wearers can communicate clearly (42CFR84.181 for powered air-purifying respirators). Note: N95 respirators without National Institute for Occupational Safety and Health (NIOSH) certification may **not** be called a NIOSH Approved N95 Respirator since specific performance testing must meet NIOSH standards as defined in 42CFR84 to be certified by NIOSH. The CDC considers unapproved respirators using "NIOSH-approved" labeling or advertising as counterfeit products. Consumers can

verify certified equipment on the NIOSH website. NIOSH is prioritizing US domestic manufacturers for approval and has issued interim guidance on approval requirements.

So we can discuss compliance with the Emergency Use Authorization (EUA) Guidelines

Face masks for non-medical uses, such as construction work or industrial applications, are not medical devices and are not FDA-regulated. They do not require FDA pre-market notification, authorization or compliance with Food Drug and Cosmetic Act (FDCA) requirements. Conversely, masks and respirators used for **medical purposes** by HCPs and the general public to reduce infectious disease transmission (e.g., for COVID-19 protection) are considered medical devices. Medical devices are regulated by the FDA and may require an FDA 510(k) (pre-market notification) or EUA application.

The Enforcement Policy for Face Masks and Respirators during the Coronavirus Disease (COVID-19) Public Health Emergency, released in April 2020 and updated in May 2020, indicates the FDA will not require premarket notification (i.e., a 510k submission) for **face masks** as long as these face masks do not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents. Face masks are not surgical respirators or surgical masks for medical use and they are NOT intended for liquid barrier protection. The FDA allows marketing and distribution of **face masks** to the general public and to in healthcare workers without prior 510(k) clearance (FDA review) even if manufactured at facilities not meeting Good Manufacturing Practices (21CFR820) as long as product labeling (among other details) meets the following EUA labeling requirements:

- identifies product as a “face mask” NOT a "surgical mask” or “respirator”
- states masks may be used when FDA-cleared or FDA-authorized masks or face coverings are unavailable
- includes no claims about flammability, antimicrobial or antiviral protection, infection prevention or reduction, or particulate filtration
- lists body contacting materials (without any drugs or biologics)
- recommends against use in surgical settings or where fluid exposure potential, infection risk or flammable potential are high

Companies manufacturing, importing, buying and selling PPE, including masks, shields and respirators, need to pay close attention to how their products are labeled to meet US regulatory requirements under temporary EUA guidelines.

Per the FDA EUA Surgical Mask Letter of Authorization, **surgical mask** labeling must meet the following EUA labeling requirements:

- specifies product is for single-use as a disposable surgical mask
- states device is not intended to replace FDA-cleared or authorized surgical masks or respirators
- lists body-contacting materials (without any drugs or biologics)
- states product is not intended for pathogenic airborne particle protection or in aerosol-generating procedures or where infectious agent inhalation exposure risk is high

- offers NO express or implied claims or statements about reuse, flammability, antimicrobial or antiviral protection, infection protection or reduction or viral filtration
- includes "Fact Sheet for Healthcare Personnel: Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic" with product

Under current PPE EUAs, surgical masks offering liquid barrier protection may be added to the Umbrella EUA for Surgical Masks (issued 05AUG2020) as an authorized surgical mask in Appendix A. Manufacturers may market authorized surgical masks without standard premarket notification provided they meet testing and labeling criteria outlined in relevant EUA guidelines. The EUA letter also waives cGMP 21CFR820 requirements for "design, manufacture, packaging, labeling, storage, and distribution" for surgical masks listed in the EUA letter, Appendix A.

For inclusion in Appendix A, a manufacturer must send performance test results, manufacturer information, product labeling, estimates of planned product numbers, a summary demonstrating products meet EUA requirements and a list of authorized importers or distributors to CDRH-nondiagnosticEUA-templates@fda.hhs.gov. To remain in Appendix A, manufacturers must maintain records, track entities receiving product, report safety/adverse events (AEs) (21CFR803), include labeling with each individual product and submit products for FDA testing upon request.

Let's review

To maintain compliance with the EUA guidance, manufacturers must understand how to define and label their products as face masks, surgical masks or respirators. Regulatory requirements vary based on product type. Face masks do not require testing or clearance, but product labels, advertising and promotional materials for any mask products for medical purposes must comply with labeling requirements for each product type. Advertising and promotional material should clearly state the masks are not FDA approved and should not suggest masks are effective for COVID-19 prevention or treatment. Labeling must also indicate surgical masks for use by HCPs as PPE (to create a physical barrier against fluids and particulates for prevention of exposure to large particles and respiratory droplets) are only authorized under EUA guidance due to surgical mask shortages. Meanwhile, the CDC encourages health care facilities to use FDA-cleared or NIOSH-approved respirator masks.

The FDA is evaluating EUA requests from domestic manufacturers as well as US companies distributing masks produced outside the US. EUA requests need to include general information, product labeling, product testing results, standards compliance, marketing authorizations from other regulatory bodies and evidence of compliance with medical device quality management systems 21CFR820 and ISO 13485. The FDA is currently allowing import of non-NIOSH-approved N95 respirators or masks meeting standards from Australia, Brazil, Europe, Japan, Korea and Mexico. KN95 respirators from China require additional evidence of standards compliance. For mask importers, please note: the FDA EUA umbrella letter specifically excludes masks manufactured in China. Importers and distributors are responsible to ensure products meet requirements for safety, performance and labeling as well as maintaining records, retaining product for testing if requested by FDA and tracking entities receiving product.

FDA maintains a special email for questions about surgical masks CDRH-COVID19-SurgicalMasks@fda.hhs.gov.

BIBLIOGRAPHY and REFERENCE LIST

1) CDC Website. *"Considerations for Wearing Masks: Help Slow the Spread of COVID-19."* Accessed 19OCT2020 at https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html

2) FDA Website. *"Emergency Use Authorization: Emergency Use Authorization (EUA) information, and list of all current EUAs."* Accessed 19OCT2020 at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

3) FDA Website. "*Face Masks and Surgical Masks for COVID-19: Manufacturing, Purchasing, Importing, and Donating Masks During the Public Health Emergency."* Accessed 19OCT2020 at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during.

4) FDA Guidance for Industry and Staff. *"Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. (Revised) (May 2020)"* Accessed 19OCT2020 at https://www.fda.gov/media/136449/download.

5) FDA 21CFR878.4040. "*Surgical Apparel*." Accessed 19OCT2020 at https://www.ecfr.gov/cgi-bin/text-idx?SID=6000bcfdbaa6acdc08171df87d35128f&mc=true&node=se21.8.878_14040&rgn=div8.

6) FDA 21CFR820. "*Quality System Regulation*." Accessed 19OCT2020 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820.

7) FDA Website. *"510(k) Clearances"* Accessed 19OCT2020 at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances.

8) FDA Webinar Transcript. *"FDA's Surgical masks Umbrella EUA" (18AUG2020)* Accessed 19OCT2020 at https://www.fda.gov/media/141609/download.

9) FDA Release. *"Product Codes and Product Code Builder"* Accessed 19OCT2020 at https://www.fda.gov/industry/import-program-resources/product-codes-and-product-code-builder.

10) FDA Product Classification. *"Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per IIe Guidance"*; QKR. Accessed 19OCT2020 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QKR.

11) FDA Product Classification. *"Mask, Surgical"*; FXX. Accessed 19OCT2020 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=2868.

12) FDA Product Classification. *"Respirator, Surgical"*; MSH. Accessed 19OCT2020 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MSH.

13) FDA Release. *"Standards and Conformity Assessment Program"* Accessed 19OCT2020 at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

14) Sprinkle, T. "*Standards for Medical Face Masks and Protective Clothing"* ASTM Standardization News, accessed on 09OCT2020 at www.astm.org/standardization-news/?q=features%2Fstandards-medical-face-masks-and-protective-clothing-.html.

15) FDA Recognized Consensus Standards. FR Recognition Number 6-406 "*ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).*" Accessed 19OCT2020 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=36979.

16) FDA Recognized Consensus Standards. FR Recognition Number 6-254. *"ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)."* Accessed 19OCT2020 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=39913.

17) FDA Recognized Consensus Standards. FR Recognition Number 6-335. *"ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus."* Accessed 19OCT2020 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=39937.

18) FDA. 21CFR1610. "*Standard for the flammability of clothing textiles*." Accessed 19OCT2020 at https://www.ecfr.gov/cgi-bin/text-idx?SID=031b1d8b662fa7c424c69b3544a17140&mc=true&node=pt16.2.1610&rgn=div5.

19) FDA Guidance for Industry and Staff. *"Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'."* Accessed 19OCT2020 at https://www.fda.gov/media/85865/download.

20) DHHS. 42CFR84.174. "*Filter efficiency level determination test – non-powered series N, R, and P filtration."* Accessed 19OCT2020 at https://www.ecfr.gov/cgi-bin/text-idx?SID=280a323f2ba53eefc846cb3827a3085c&node=se42.1.84_1174&rgn=div8.

21) DHHS. 42CFR84.181. *"Communication performance test – PAPR class PAPR100."* Accessed 19OCT2020 at https://www.ecfr.gov/cgi-bin/text-idx?SID=280a323f2ba53eefc846cb3827a3085c&node=se42.1.84_1181&rgn=div8.

22) CDC Release. *"Standard Respirator Testing Procedures"* Accessed 19OCT2020 at https://www.cdc.gov/niosh/npptl/stps/respirator_testing.html.

23) CDC Release. *"Counterfeit Respirators/Misrepresentation of NIOSH-Approval"* Accessed 19OCT2020 at https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.

24) CDC Website: *"Certified Equipment List Search"* Accessed 19OCT2020 at https://www2a.cdc.gov/drds/cel/cel_form_code.asp.

25) CDC Website. *"NIOSH Conformity Assessment Letter to Manufacturers"* (NIOSH CA 2020-1031) Accessed 19OCT2020 at https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2020-1031.html.

26) CDC Website. *"NIOSH Conformity Assessment Letter to Manufacturers"* (NIOSH CA 2018-1010R1.0) Accessed 19OCT2020 at https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2018-1010-R1.html.

27) FDA Website. "*Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised).*" Accessed 19OCT2020 at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health

28) FDA. *"EUA Letter of Authorization"* (Umbrella EUA for Surgical Masks). Accessed 19OCT2020 at https://www.fda.gov/media/140894/download.

29) FDA. *"Fact sheet for healthcare personnel."* Accessed 19OCT2020 at https://www.fda.gov/media/140895/download.

30) FDA Website. *"Appendix A: Authorized Surgical Masks"* within *"Personal Protective Equipment EUAs"* Accessed on 19OCT2020 at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks

31) FDA. 21CFR803. *"Medical Device Reporting."* Accessed 19OCT2020 at https://www.ecfr.gov/cgi-bin/text-idx?SID=a5049aa474dbe4a156daf2912a079d5b&mc=true&node=pt21.8.803&rgn=div5.

32) ISO. ISO 13485:2016. *"Medical devices – Quality management systems – Requirements for regulatory purposes."* Accessed 19OCT2020 at https://www.iso.org/standard/59752.html.

33) FDA Release. *"FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic"* Accessed on 17SEP2020 at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic.

34) FDA Release. *"FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical)"* Accessed on 09OCT2020 at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical.

35) FDA Release. *"Information for Filing Personal Protective Equipment and Medical Devices During COVID-19"* Accessed on 09OCT2020 at https://www.fda.gov/industry/importing-covid-19-supplies/information-filing-personal-protective-equipment-and-medical-devices-during-covid-19.

36) FDA Release. *"Importing COVID-19 Supplies"* Accessed on 09OCT2020 at https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/importing-covid-19-supplies.

37) FDA Website: “N95 Respirators, Surgical Masks, and Face Masks” Accessed on 29SEP2020 at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks.

38) FDA Release. *“Registration and Listing of Medical Devices during the COVID-19 Pandemic”* Accessed on 09OCT2020 at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/registration-and-listing-medical-devices-during-covid-19-pandemic#e%E2%80%A6.