



March 6, 2023

To: Manufacturers of Surgical Masks;
Health Care Personnel;
Hospital Purchasing Departments;
Authorized Distributors and Authorized Importers; and
Any Other Stakeholders

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).¹ Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.²

On August 5, 2020, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for disposable, single-use surgical masks^{3, 4} (hereafter also referred to as “surgical masks”) for use in healthcare settings by healthcare personnel (HCP)⁵ as personal

¹ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 7, 2020).

² U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 17335 (March 27, 2020).

³ A surgical mask is a mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks are generally regulated by FDA as Class II devices under 21 CFR 878.4040 – Surgical apparel.

⁴ FDA-cleared surgical face masks, non-surgical face masks, surgical masks with antimicrobial/antiviral agent, and all particulate filtering facepiece respirators are not within the scope of this authorization.

⁵ For the purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

protective equipment (PPE)⁶ to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, pursuant to section 564 of the Act (21 U.S.C. 360bbb-3).

Since August 5, 2020, FDA has continued to periodically review the circumstances and the appropriateness of authorizing the emergency use of surgical masks under this EUA as required by section 564(g)(1) of the Act. FDA has now determined that revision and reissuance of this EUA is appropriate, based on the totality of scientific evidence available, which includes information regarding supply, demand and distribution, and information compiled from requests for addition of surgical masks to [Appendix A](#)⁷ of the EUA, premarket submissions, and imports data. Based on this review and all available information, FDA has concluded that the criteria for issuance under section 564(c) of the Act are met with respect to the surgical masks listed in [Appendix A](#) as of the date of this reissuance. In doing so, FDA has determined that it is appropriate to revise the scope of this authorization. As such, pursuant to section 564(g)(2)(C) of the Act, and as outlined in Section II of this letter, the scope is being revised such that no additional surgical masks will be added to [Appendix A](#).

Having concluded that revising the August 5, 2020 letter is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the August 5, 2020 letter in its entirety⁸ with the revisions⁹ incorporated to authorize the emergency use of authorized surgical masks in [Appendix A](#). No additional surgical masks will be added to [Appendix A](#) as a result of this revision.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the authorized surgical masks that are in [Appendix A](#) as set forth in Section II pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized surgical masks listed in [Appendix A](#) meet the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

⁶ Surgical masks may be effective in blocking splashes and large particle droplets. While surgical masks are not protective against smaller airborne particulates as described in Section II, they are considered PPE because they are intended to be used to protect HCP from infectious disease hazards. Surgical masks are different from non-surgical face masks, which are only used as source control by the general public and are not considered PPE.

⁷ Appendix A: Authorized Surgical Masks is available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks>.

⁸ This letter, which was originally issued on August 5, 2020, is being reissued in its entirety.

⁹ The March 6, 2023, revisions to the August 5, 2020, letter removes the eligibility criteria so that no additional surgical masks will be added to Appendix A.

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks listed in [Appendix A](#) may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of this authorization (Section II), outweigh the known and potential risks of such products; and
3. There is no adequate, approved, and available alternative to the emergency use of these authorized surgical masks for use in healthcare settings by HCP to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.^{10,11}

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized surgical masks listed in [Appendix A](#), for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.

Surgical masks are not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators. Surgical masks may be effective in blocking splashes and large-particle droplets; however, because of the loose fit between the surface of the surgical mask and the user's face, leakage can occur around the edge of the mask when the user inhales. Therefore, a surgical mask may not provide the user with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection. For this reason, surgical masks are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure. In such clinical conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit is recommended to provide a more reliable level of respiratory protection against pathogenic biologic airborne particulates.

¹⁰ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

¹¹ Though supply and demand are stabilizing and there is an increased number of FDA-cleared alternatives available, there are not sufficient quantities of 510(k) cleared surgical masks to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic. Providing continued authorization for the surgical masks listed in Appendix A helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

The Authorized Surgical Masks

Surgical masks authorized by this EUA¹² for the above-described intended use are currently listed in [Appendix A](#). All authorized surgical masks listed in [Appendix A](#) were listed in [Appendix A](#) at the time of this reissuance and meet the following performance criteria:

- Fluid resistance requirements (liquid barrier performance) consistent with ASTM F1862: *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*; ¹³
- Flammability performance consistent with the definition of either a Class 1 or Class 2 textile in 16 CFR Part 1610;
- Particulate filtration efficiency requirements consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks*;
- Air flow resistance (i.e., breathability) requirements with an acceptance criterion of <6 mm H₂O/cm² for differential pressure (delta P) testing consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers; and
- The materials of manufacture are either (1) non-cytotoxic, non-irritating and non-sensitizing consistent with the recommendations in FDA’s guidance, “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’”¹⁴ or (2) conform to the following biocompatibility standards:
 - ISO 10993-1: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
 - ISO 10993-5: *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
 - ISO 10993-10: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.*

The labeling of the authorized surgical masks must:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);

¹² Surgical masks that were: (1) FDA-cleared; (2) manufactured in China; or (3) included drugs, biological, nanoparticles or antimicrobial/antiviral agents were excluded from the scope of the August 5, 2020 letter, and were not authorized under this EUA.

¹³ For the current edition of the FDA-recognized consensus standards referenced in this document, see the FDA Recognized Consensus Standards Database, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. For more information regarding use of consensus standards in regulatory submissions, refer to the FDA guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

¹⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>.

- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators;
- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure; and
- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency.

Authorized products must be accompanied by the above required labeling, and in addition, the authorized products must be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to HCPs:

- Fact Sheet for Healthcare Personnel: Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic

The manufacturer's labeling (which must meet the labeling requirements specified above) and the fact sheet, are referred to as "authorized labeling."

Authorized products are subject to surveillance and monitoring. FDA may remove an authorized surgical mask from [Appendix A](#) of this EUA if FDA has reason to believe that the product no longer meets the Scope of Authorization (Section II). FDA will provide the manufacturer 24 hours advance notice of such removal. Products that are removed from [Appendix A](#) will be included on a list maintained on FDA's EUA webpage.

The above-described authorized surgical masks listed in [Appendix A](#) are authorized to be distributed to and used in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized surgical masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that authorized surgical masks may be effective as described within this section (the Scope of Authorization, Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that authorized surgical masks (as described in the Scope of Authorization, Section II), meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized surgical masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), surgical masks that are determined to meet the criteria set forth in this section (Section II) are authorized under the terms and conditions of this EUA.

III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized surgical masks that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers of Authorized Products

- A. Manufacturers must make authorized products available with the authorized labeling (including the labeling requirements described in Section II). Manufacturers must make available all labeling in English, to each end user facility (e.g., each hospital) that receives the authorized products, and may include the authorized labeling with each individual authorized product.
- B. Manufacturers must comply with 21 CFR Part 803, and must have a process in place for reporting adverse events of which they become aware to FDA consistent with 21 CFR Part 803. See FDA's webpage "[Medical Device Reporting \(MDR\): How to Report Medical Device Problems](https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems)"¹⁵ for additional information concerning reporting requirements under 21 CFR Part 803 and procedures.
- C. Manufacturers must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

¹⁵ FDA's webpage titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

- D. Through a process of inventory control, manufacturers must maintain records of the entities to which they distribute the surgical masks and the numbers of each such product they distribute.
- E. Manufacturers must notify FDA of any authorized distributor(s) and/or authorized importers of the authorized surgical masks, including the name, address, and phone number of any authorized distributor(s) and authorized importer(s), and provide authorized distributor(s) and authorized importer(s) with a copy of this EUA and any updates.
- F. Manufacturers are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.
- G. Manufacturers of authorized surgical masks must submit, upon FDA's request, new lots of the authorized surgical masks for testing by FDA or by another entity designated by FDA. The manufacturers must not distribute any lot or shipment that fails testing, meaning the lot or shipment containing a lot that did not perform as expected based on the performance criteria in the Scope of Authorization (Section II). FDA will make the manufacturer aware of the testing results.

Authorized Distributors and Authorized Importers¹⁶

- H. Authorized Distributors and Authorized Importers must ensure that authorized surgical masks comply with condition A of this EUA.
- I. Through a process of inventory control, Authorized Distributors and Authorized Importers must maintain records of the entities to which they distribute the surgical masks and how many of each authorized product model they distribute or import, as applicable.
- J. Authorized Distributors and Authorized Importers must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- K. Authorized Distributors and Authorized Importers of authorized surgical masks must submit, upon FDA's request, lots or shipments of the authorized surgical masks for testing by FDA or by another entity designated by FDA. Authorized Distributors and Authorized Importers must not distribute any lot or shipment that fails testing, meaning the lot or shipment containing a lot that did not perform as expected based on the performance criteria in the Scope of Authorization (Section II). FDA will make the Authorized Distributor or Authorized Importer aware of the testing results.

¹⁶ "Authorized Distributor(s)" and "Authorized Importer(s)" are those that are identified by the manufacturer in Condition of Authorization E.

Conditions Related to Advertising and Promotion

- L. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized surgical mask shall be consistent with the labeling requirements listed in Section II and this section (Conditions of Authorization) of this EUA, and meet the applicable requirements set forth in section 502(a) and (q)(1) and (r) of the Act, as applicable, and FDA implementing regulations.
- M. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized surgical mask may represent or suggest that such product is safe or effective for the prevention or treatment of COVID-19.
- N. All descriptive printed matter, including advertising and promotional materials, relating to the use of the product shall clearly and conspicuously state that:
- The product has not been FDA cleared or approved.
 - The product has been authorized by FDA under an EUA for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.
 - This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration