

Personal Protective Equipment EUAs

Personal Protective Equipment (</medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control>) refers to protective clothing, helmets, gloves, face shields, goggles, respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued EUAs for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. Additionally, the FDA has issued recommendations and policies about PPE which can be found here: [Recent Final Medical Device Guidance Documents \(/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents\)](/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents).

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA, including an [Interactive Review Template For Non-IVD Products \(/media/137965/download\)](/media/137965/download). Additionally, the FDA has posted a [Surgical Masks EUA Template for Addition to Appendix A \(/media/140896/download\)](/media/140896/download) of the Surgical Mask Umbrella EUA.

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Umbrella EUA for Surgical Masks

On August 5, 2020, the FDA issued an umbrella emergency use authorization (EUA) for certain disposable, single-use surgical masks in response to concerns relating to insufficient supply and availability of such masks. This EUA authorizes the emergency use of surgical masks that meet certain performance requirements for use in healthcare settings by health care personnel as personal protective equipment 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 that have been confirmed by FDA to meet the criteria under the EUA are included below in Appendix A as authorized surgical masks.

- [EUA Letter of Authorization - Umbrella EUA for Surgical Masks \(/media/140894/download\)](/media/140894/download)
- [Fact Sheet for Healthcare Personnel \(/media/140895/download\)](/media/140895/download)
- [Appendix A: Authorized Surgical Masks](#)

The [Surgical Masks EUA Template for Addition to Appendix A \(/media/140896/download\)](/media/140896/download) can be used to provide the information requested in the EUA to the FDA.

Appendix A: Authorized Surgical Masks

The table below includes a list of surgical masks authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.



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Date of Addition	Manufacturer	Authorized Product Name (including model numbers)
11/06/2020	EcoGuard Inc.	Surgical Mask - Disposable Single-Use 3-Ply Earloop Model #: EcoGuard B ECO01 Surgical Mask - Disposable Single-Use 3-Ply Tie-on Model #: EcoGuard B ECO02 Surgical Mask - Disposable Single-Use 4-Ply Earloop Model #: EcoGuard A ECO03 Surgical Mask - Disposable Single-Use 4-Ply Tie-on Model #: EcoGuard A ECO04
11/03/2020	Fischer Manufacturing, LLC	Heartland Health Surgical Mask
10/28/2020	SIO International Wisconsin, Inc.	Sharp MQ-3050 Surgical Mask Foxconn MQ-3050 Surgical Mask
10/15/2020	Premium-PPE Amerishield	Premium PPE Amerishield Disposable Surgical Mask Model #: PPE-M-AS-SUR-lvl2-S
10/15/2020	Brandix Apparel Solutions Limited	Disposable Surgical Mask BRNDX-DSM-001-LARGE
10/08/2020	WPT Corporation	WPT ASTM F2100-19 Level 3 Earloop Surgical Face Mask (Model # SMS2020)
10/05/2020	Hanesbrands, Inc.	Hanes Surgical Mask 01, Small and Large
09/19/2020	Premier Guard USA LLC	Premier Guard USA Surgical Face Mask 20-1002-SFM3
08/18/2020	Venus Group, Inc.	Venus Medical Grade Disposable Surgical Mask
08/08/2020	Outdoor Research	Outdoor Research Surgical Mask model #OR2159

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N95 and Other Respirators EUAs (including EUAs for NIOSH-Approved N95s and imported respirators)

The table below includes information about respirators authorized for emergency use by healthcare personal during the COVID-19 public health emergency.

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Date EUA Issued	PPE (Letter of Authorization)	Other Documents
03/28/2020	NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency (/media/135763/download)	<ul style="list-style-type: none"> EUA Clarification Letter on Respirators (/media/136023/download)

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Umbrella EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) Manufactured in China (Reissued October 15, 2020)

On April 3, 2020, the FDA issued an umbrella EUA for certain filtering face-piece respirators (FFRs) that are manufactured in China and are not approved by the National Institutes of Occupational Safety and Health (NIOSH). As mentioned in CDC's strategies for optimizing respirator supply (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html>), other countries approve respirators according to country-specific standards. These devices are evaluated using methods similar to those used by NIOSH and are still expected to provide adequate protection for healthcare personnel. Non-NIOSH-approved FFRs manufactured in China that have been confirmed by FDA to meet the criteria under the EUA are included below in Appendix A.

As part of the government's continuous quality assessment of these respirators, the FDA, working with CDC NIOSH, conducted additional assessments and found that some of the respirators authorized under the April 3, 2020 EUA did not meet the expected performance standards. In response, the FDA revised and reissued the EUA on May 7, 2020 to among other revisions, revise the third criterion for eligibility. Additionally, the FDA, in collaboration with CDC NIOSH, is increasing surveillance and sampling of all respirators imported from China - all respirator shipments from China that come into the U.S. will be subject to random sampling and testing by CDC NIOSH to determine whether the respirator meets the expected particulate filtration standards.

On June 6, 2020 the FDA further revised the Scope of Authorization of this EUA, to among other changes, further revise the third eligibility criterion, revise the second eligibility criterion, and remove decontaminated respirators from the scope of authorized products such that authorized respirators listed in Appendix A will no longer be authorized if they are decontaminated.

On October 15, 2020, the FDA reissued the Emergency Use Authorization (EUA) for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to authorize for emergency use only those respirators listed in the EUA's Appendix A as of the date of this reissuance. Effective immediately, this EUA no longer includes the three eligibility criteria that were included in the previous June 6, 2020 authorization letter, meaning the FDA will no longer be reviewing requests and adding new respirator models to Appendix A based on those criteria. Further explanation of the revisions can be found in the Frequently Asked Questions (FAQs) about Non-NIOSH-Approved Filtering Facepiece Respirators (</medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic>).

- [EUA Letter of Authorization - Umbrella EUA: Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China \(/media/136664/download\)](/media/136664/download) (Reissued October 15, 2020)
- [Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA FAQs \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic\)](/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic)
- [Appendix A: Authorized Respirators, Non-NIOSH Respirators Manufactured in China \(Updated October 15, 2020\)](#)
- [Respirator Models No Longer Authorized \(Updated October 15, 2020\)](#)

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated: October 15, 2020)

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The table below includes a list of non-NIOSH respirators authorized by this Umbrella EUA (/media/136664/download) for emergency use during the COVID-19 public health emergency.

As stated in the EUA, authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html).

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Manufacturer	Respirator Model(s)	Instructions for Use
3M	9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V	<ul style="list-style-type: none"> 9001: IFU (https://multimedia.3m.com/mws/media/18276350/3m-particulate-respirator-9001-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9002: IFU (https://multimedia.3m.com/mws/media/18276360/3m-particulate-respirator-9002-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9501: IFU (https://multimedia.3m.com/mws/media/18276330/3m-particulate-respirator-9501-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9501+: IFU (https://multimedia.3m.com/mws/media/18276310/3m-particulate-respirator-9501-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9501V+: IFU (https://multimedia.3m.com/mws/media/18276300/3m-particulate-respirator-9501v-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9502: IFU (https://multimedia.3m.com/mws/media/18267850/3m-particulate-respirator-9502-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9502+: IFU (https://multimedia.3m.com/mws/media/18288690/3m-particulate-respirator-9502-user-instructions-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9502V+: IFU (https://multimedia.3m.com/mws/media/18267830/3m-particulate-respirator-n95-9502v-ui-for-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9505+: IFU (https://multimedia.3m.com/mws/media/18276320/3m-particulate-respirator-9505-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9541: IFU (https://multimedia.3m.com/mws/media/18276340/3m-particulate-respirator-9541-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9541V: IFU (https://multimedia.3m.com/mws/media/18276290/3m-particulate-respirator-9541v-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9542: IFU (https://multimedia.3m.com/mws/media/18267860/3m-particulate-respirator-9542-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9542V: IFU (https://multimedia.3m.com/mws/media/18267890/3m-particulate-respirator-9542v-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9552: IFU (https://multimedia.3m.com/mws/media/18258570/3m-95-5-2-particulate-respirator-n95-user-instruction-eua-website.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9552V: IFU (https://multimedia.3m.com/mws/media/18268070/3m-particulate-respirator-9552v-ui-eua.pdf) ⌕ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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Manufacturer	Respirator Model(s)	Instructions for Use
Allmed Medical Products Co., Ltd	LP220002	<ul style="list-style-type: none"> IFU (http://www.allmed-china.com/index.php?m=content&c=index&a=show&catid=20&id=33) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
AnDum Protective Equipment Technology (Changzhou) Co.,Ltd.	AD-1001	<ul style="list-style-type: none"> IFU (http://www.an-dum.com/index.php?m=content&c=index&a=show&catid=184&id=158) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Anhui Hanxiutang Biotechnology Co., Ltd.	HXT-01	<ul style="list-style-type: none"> IFU (http://www.ahhxt.cn/en/Products/Product_categories_1/16.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
ANHUI JIABAO PROTECTIVE EQUIPMENTS CO.,LTD	JB-RP001	<ul style="list-style-type: none"> IFU (http://en.jiabaohyp.com/display/432588.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Anhui Jinrui Auto Parts Co., Ltd.	JR-01	<ul style="list-style-type: none"> IFU (http://www.jinruikeji.com/cn/jksy/index_138.aspx) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Anhui Zhongke Duling Commercial Appliance Co. Ltd	M-9501	
Anshun Health and Medical Technology Co., Ltd.	AKF6002	<ul style="list-style-type: none"> IFU (http://www.runbomask.com/AKF6002-FFP2-NR/AKF6002FFP2NR-1.shtml) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
AOK Tooling Ltd. (aka Shenzhonghai Medical)	20130040, 20130045A, 20180021, 20130038, 20190019, 910, 20190029	<ul style="list-style-type: none"> 20130040: IFU (http://www.toolingexpress.com/images/20130040-InstructionsforUse.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 20130045A: IFU (http://www.toolingexpress.com/images/20130045-InstructionsforUse.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 20180021: IFU (http://www.toolingexpress.com/images/20180021-InstructionsforUse.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 20130038: IFU (http://www.toolingexpress.com/images/20130038-InstructionsforUse.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 20190019: IFU (http://www.toolingexpress.com/images/20190019-InstructionsforUse.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 910: IFU (http://www.toolingexpress.com/images/910-Instruction.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 20190029: IFU (http://www.toolingexpress.com/images/20190029-Instruction.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.	YH/KN95-1	
Bei Bei Safety Co Ltd.	B702, B702V, B704, B704V	<ul style="list-style-type: none"> IFU (https://www.beibeisafety.com/upload/download/200515212549000002.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Beifa Anhui Manufacturing Co., Ltd.	BF-A-01	<ul style="list-style-type: none"> IFU (http://www.beifa.com/en/productsd.php?tid=1227&pid=6417) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Manufacturer	Respirator Model(s)	Instructions for Use
Beijing Topnew Import & Export Co., Ltd.	ZY95	<ul style="list-style-type: none"> IFU (http://ie.topnew.cn/english/productf.aspx?from=groupmessage&isappinstalled=0) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
BG PRECISION CO. LTD	KN95-N	<ul style="list-style-type: none"> IFU (http://www.bgprecision.cn/news-16-1.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
BYD Precision Manufacture Co. Ltd.	DG3101, DN1102	<ul style="list-style-type: none"> DG3101: IFU (https://www.byd.care/pages/kn95) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) DN1102: IFU (https://www.byd.care/pages/kn95-respirator) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Careable Biotechnology Co., Ltd.	CARE002, CARE003	<ul style="list-style-type: none"> IFU (https://www.careablemask.com/aboutus/37115.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Carte Medical Equipment (Suzhou) Co., Ltd	K8201	<ul style="list-style-type: none"> IFU (http://www.carteholding.com/page.asp?id=854) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Changsha Changjiu Medical Technology Co. Ltd.	KN95-05, KN95-08	<ul style="list-style-type: none"> IFU (http://www.hncjmed.com/articles/2286/2020-7/65216.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Changshu Dayi Health Protection Articles Co., Ltd	DY-3	<ul style="list-style-type: none"> IFU (http://en.dayimedical.cn/use.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Chengde Technology Co.	KN95	
Chongqing China Nano Technology Co., Ltd.	ZN6005	<ul style="list-style-type: none"> IFU (http://www.zhongnakeji.com/product/namixianweixincailiao/61.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Chongqing Zisun (Zaisheng) Technology Corp., Ltd.	ZS-ZD-FJ-1, ZS-ZD-WJ-1	<ul style="list-style-type: none"> IFU (https://en.cqzskj.com/news/news_show/?id=5579&cid=1306The) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Creative Concepts Manufacturing Ltd. aka Huizhou RD Plastic Co., Ltd	02676	<ul style="list-style-type: none"> IFU (https://www.medicconceptsgroup.com/kn95/manual/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Deli Group Co., LTD.	ET30000	
DONGGUAN AOXING AUDIO VISUAL EQUIPMENT CO.,LTD	AX-KF95	
Dongguan Arun Industrial Co., LTD	KN95 N9	<ul style="list-style-type: none"> IFU (http://www.all-round.com.cn/ProductView.Asp?ID=27) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan City Outdoorsy Co., Ltd.	OD-001	<ul style="list-style-type: none"> IFU (http://www.outdoorsy360.com/product/pro1/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan Pan American Electronics Co., Ltd.	KN95-01, KN95-02, N1001	

Manufacturer	Respirator Model(s)	Instructions for Use
Dongguan Rysam Medical Equipment Manufacturing Co.	Particle Filtering half mask RSN95B, Particle Filtering half mask RSN99V	• IFU (https://www.rysam.cn/eua)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan Sengtor Plastics Products Co., Ltd.	KN95	• IFU (https://www.sengtor.com/instructions-for-use)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Donghua Siecom Communication Technology Co.,Ltd	ZGKNM-01	• IFU (https://www.siecom.cn/?app=survival&act=details&id=89)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
ESound Medical Device Co., Ltd.	20182140615 Folded	• IFU (http://www.e-soundmed.com/h-pd-130.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
FOSHAN FLOCON MEDICAL EQUIPMENTS CO., LTD	M1	
Foshan Nanhai Chuanzhishang Clothing Co., LTD	CZ-S02	
Fujian Dahong Industrial Development Co. Ltd.	PGT-0095	
Fujian Leephick Pharmaceutical Industry Co. Ltd.	KPM-3	• IFU (https://www.leephick.com/product/ffp2_filtering_half_mask_headband_/133.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Fujian Yifa Healthcare Products Co., Ltd.	Y195	• IFU (https://en.newyifagroup.com/article/90.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Fujian Yongtai Sanlian Garment Co., Ltd.	N95 Particulate Respirator (Xier)	
Fuzhou Chunlan Medical Equipment Co., Ltd.	CL-P1	• IFU (http://www.fjchunlan.com/en/pd.jsp?id=14)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong GangRong Medical Technology Co., Ltd	GR200	• IFU (http://www.gdgrmt.com/blog-single4.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
GUANGDONG GOLDEN LEAVES TECHNOLOGY DEVELOPMENT CO., LTD.	8862 KN95	• IFU (http://www.cnjymedical.com/detail?id=8862)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
GUANGDONG JINGCOS CO., LTD	95J1	
Guangdong KINGFA SCI. & TECH. Co. Ltd.	KF-A F01, KF-A F10(SC)	• IFU (http://www.kingfa.com/en/respirator3/642.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Manufacturer	Respirator Model(s)	Instructions for Use
Guangdong Languan Medical Biotechnology Co., Ltd.	LGKN95	<ul style="list-style-type: none"> IFU (http://www.blueguan.com.cn/cn/produ/Product_Instruction/index.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Nuokang Medical Technology Co., Ltd.	KN95 Non-Surgical Disposable Particulate FFR	<ul style="list-style-type: none"> IFU (https://www.nuokang.net/respirator?product_id=9)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Seyouse Technology and Culture CO.,LTD	SS-001	
Guangdong Tengrui Pharmaceutical Technology Co., Ltd.	LSH-201	
Guangdong Willing Technology Corporation	WL-01	
Guangdong Winsun Personal Care Products Co., Ltd.	YS0003	<ul style="list-style-type: none"> IFU (https://gdwinsun.en.made-in-china.com/product/qOQEPHjWEUVw/China-Protective-Ys0003-Filter-in-Stock-Face-Mask-with-FFP2-Approved.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Yidao Medical	YD-002	<ul style="list-style-type: none"> IFU (http://www.superyidao.com/en/product/product-44-633.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Zhizhen Biological Medicine Co., Ltd.	KN95 Three-Dimensional Protective Face Mask	<ul style="list-style-type: none"> IFU (http://www.zhizhenmedic.com/instruction.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangxi MC Medical equipment Co., Ltd	MC010501	<ul style="list-style-type: none"> IFU (http://www.mcmedical.net/en/h-pd-3.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO.,LTD	MY3D2	<ul style="list-style-type: none"> IFU (http://www.baifeier.com.cn/en/article-28481-41890.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangzhou Bofeite Safety Protective Supplies Co., Ltd.	HT9510V, HT9510	
Guangzhou Carrot Mall Network Technologies Co., Ltd.	IRYS-01	<ul style="list-style-type: none"> IFU (http://www.ivrou.com/images/Intended_Use_and%20Other_Instructions_of_IVROU.pdf)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangzhou Harley Commodity Company Limited	L-103V KN95	
Guangzhou Nan Qi Xing Non-Woven Co., Ltd.	KN-1 Respirator	<ul style="list-style-type: none"> IFU (https://www.gznqx.com/china-qn95-china-masks-customized-nanqixing)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangzhou Powecom Labor Insurance Supplies Co., LTD	KN95	<ul style="list-style-type: none"> IFU (http://www.powecom.com/eng_product.html)  (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Manufacturer	Respirator Model(s)	Instructions for Use
Guanyang Yunhan Textile Co., Ltd.	YH-9500	<ul style="list-style-type: none"> IFU (http://www.yohansupplies.com/en/?p=page&sortid=263&typeid=302&pid=3698&showlist=2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Haishi Hainuo Lexiang Medical Technology (Qingdao) Co., Ltd.	LX1001	
HANGZHOU FILTECH INTELLIGENT CO., LTD.	Filtech Face Mask Model F860, F862, F890V, F891V, F890, F861	<ul style="list-style-type: none"> F860: IFU (http://www.filtech.cn/filtechmask/FFP2/F860.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) F862: IFU (http://www.filtech.cn/filtechmask/FFP2/F862.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) F890V: IFU (http://www.filtech.cn/filtechmask/FFP3/F890V.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) F891V: IFU (http://www.filtech.cn/filtechmask/FFP3/F891V.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hangzhou Gang Yu Health Products Co., Ltd.	GY2020001	<ul style="list-style-type: none"> IFU (http://www.gywsyp.com/index.php/product/detail/53.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hangzhou San Qiang Safety Protection Products Co., Ltd.	9420 (FFP2), 9420V (FFP2), 9480 (FFP2), 9450B, 9480V (FFP2), 9980V (FFP3), 9920V (FFP3)	<ul style="list-style-type: none"> 9420 (FFP2), 9420V (FFP2), 9480 (FFP2), 9480V (FFP2): IFU (http://www.qqq-ppe.com/public/upload/certification/20200708/914f310e94bb5508cc1e8396d83aeb55.jpg) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 9980V (FFP3), 9920V (FFP3): IFU (http://www.qqq-ppe.com/public/upload/certification/20200708/9f0bcbe3a824a8b44d64978dd83d32ea.jpg) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hebei Pengyuan Optoelectronics Co., Ltd.	SUPERNOVA-P2	<ul style="list-style-type: none"> IFU (https://www.china-supernova.com/sale-13193847-face-mask-instructions-for-model-supernova-p2.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Henan Akily Filter Engineering Co., Ltd.	KZ888E	<ul style="list-style-type: none"> IFU (http://www.hnsakily.com/eng/news/4_119) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Henan Bingzun Industrial Co.,Ltd.	8410	<ul style="list-style-type: none"> IFU (http://m.zunyue188.com/kz222/vip_doc/17753275.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Henan Yadu Industrial Co., Ltd	Flat Fold	<ul style="list-style-type: none"> IFU (http://www.yadu-medical.com/new/new-43-284.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Heyuan COE Communication Technology Co., Ltd.	CHMM-NB	<ul style="list-style-type: none"> IFU (http://www.hycoe.com/showpro.asp?ID=65) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hubei Huaqiang High-Tech Co., Ltd.	Flat Fold (Earloop) Non-Sterile	<ul style="list-style-type: none"> IFU (http://www.huaqiang.world/23341.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hui Zhou Tian Chang Industrial Co., Ltd.	N002-AW	<ul style="list-style-type: none"> IFU (https://carewe.store/pages/instruction-for-use-n002-aw-ffp2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Manufacturer	Respirator Model(s)	Instructions for Use
Huizhou Green Communication Equipment Manufacturing Co., Ltd	G95200 Particle Filtering Half Mask	<ul style="list-style-type: none"> IFU (http://www.green-cem.com/en/productsDetail.php?id=13) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Huizhou Huinuo Technology Co., Ltd	9501A	<ul style="list-style-type: none"> IFU (http://www.hvn-china.com/en/pro/kn95/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Huizhou Yibaidu Medical Device Technology Co., Ltd.	YBD-2	
Hunan Boltpower Guokang Medical Equipment Co., Ltd.	GK-002A	<ul style="list-style-type: none"> IFU (http://www.djjgkyl.com/product/11.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hunan Changyuan Technology Co., Ltd.	CY005 Filtering Half Mask	<ul style="list-style-type: none"> IFU (https://dcmask.com/ffp2-face-mask/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hunan EEXI Technology & Service Co., Ltd.	YX152, YX153	
Hunan Hengchang Pharmaceutical Co., LTD.	N9501-L (non-sterile type)	
Hunan Kangweining Medical Devices Co., Ltd.	YH-I (non-sterile) and YH-II (sterile)	
Hunan Yianyuan Medical Science and Technology Co. Ltd.	JY009A	<ul style="list-style-type: none"> IFU (http://en.jyylkj.com/product/58.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiande Chaomei Daily Chemicals Co.	F-Y3-A	<ul style="list-style-type: none"> IFU (http://www.cmmask.net/products/details/yyfhkz-135.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangmen Nostop Electric Co., Ltd	JW-017	<ul style="list-style-type: none"> IFU (http://www.nostop.cn/InformationofourEUAListedrespirator.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
JIANGSU CHANGMEI MEDTECH CO.,LTD	DFM-01	<ul style="list-style-type: none"> IFU (http://www.czmed.com/index.php?option=com_k2&view=itemlist&layout=category&task=category&id=229&Itemid=744&lang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
JiangSu EverSmart Nano Technology Co., Ltd.	HZ-KN95	<ul style="list-style-type: none"> IFU (http://www.eversmartnano.com/article-detail/bLARp49B) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
JIANGSU HOMCAN MEDICAL TECHNOLOGY CO. LTD	HC-NP95A	<ul style="list-style-type: none"> IFU (https://www.homcan.cn/FFP2-instructions) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangsu Jiaao Medical Technology Co., Ltd.	JA95-1 Filtering half mask	<ul style="list-style-type: none"> IFU (http://www.jiaaomed.cn/pd.jsp?id=7) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Manufacturer	Respirator Model(s)	Instructions for Use
Jiangsu Kangershun Protective Equipment Co., Ltd.	KES-002	<ul style="list-style-type: none"> IFU (https://fdamaster.com/kes-002-user-instruction/) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangsu Sanfo Outdoor Products Co., Ltd	CX9501-P	
Jiangsu Yimao Filter Media Co., Ltd	9570K, 9560K	<ul style="list-style-type: none"> IFU (https://www.eimoeco.com/pd42376175.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiaxing Yinuo Busway Co., Ltd.	YJ-P2	
Jingzhou Strong Sciences & Technology Development Co.,Ltd	ST-A9502, A9507	<ul style="list-style-type: none"> ST-A9502: IFU (http://www.jzstrong.com/enshop/bencandy.php?fid=3&id=197) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) A9507: IFU (http://www.jzstrong.com/enshop/bencandy.php?fid=3&id=198) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinhua Ai Kou Protective Equipment Co.,	AK003	<ul style="list-style-type: none"> IFU (http://www.aaikou.com/aaikou/products/18974771.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinhua Jiadaifu Medical Supplies Co., Ltd.	Disposable Non-Medical Face Mask (KN95)	<ul style="list-style-type: none"> IFU (http://www.jiadf.com/a.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinwells (Tianjin) Science and Technology Co., Ltd.	JWS-1, JWS-2	<ul style="list-style-type: none"> JWS-1: IFU (http://www.jinwells.com/default.aspx?pageid=14&pageType=detail&id=59) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) JWS-2: IFU (http://www.jinwells.com/default.aspx?pageid=14&pageType=detail&id=60) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinyi (Tianjin) Medical Technology Co., Ltd.	JYKN9501	
Lanshan Shendun Technology Co., Ltd.	SD-KN95	<ul style="list-style-type: none"> IFU (http://en.lamdownmask.com/article/1013/1005) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Liaoning Dalian Jieying Energy Saving Environmental Protection Technology Development Co., Ltd.	JY-FH-F, JY-FH	<ul style="list-style-type: none"> JY-FH-F: IFU (https://www.jieyingtechnology.com/Content/show/catid/109/id/17/lang/en.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) JY-FH: IFU (https://www.jieyingtechnology.com/Content/show/catid/88/id/14/lang/en.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Lu'an Bi Hai Protective Equipment Co., Ltd.	BH2020	
Meizhuangchen Health Technology (Shenzhen) Co., Ltd.	ENKN95-001	

Manufacturer	Respirator Model(s)	Instructions for Use
Naton Medical Protective Mask (Zhuozhou) Co., Ltd	FS9501-L, FS9501-M, FS9501-S; FS9901-L, FS9901-M, FS9901-S	
ORICH Medical Equipment (Tianjin) Co., Ltd.	N95 Folded Form (Non-sterile)	<ul style="list-style-type: none"> IFU (https://www.orichmed.com/particulate-respirator-583.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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Respirator Models Removed from Appendix A (Respirator Models No Longer Authorized)

These respirator models had been on the list of authorized respirators in Appendix A but no longer meet the EUA (<https://www.fda.gov/media/136664/download>) eligibility criteria and thus are no longer authorized. Note: As outlined in the EUA, a respirator model with a removal date of May 7, 2020 is eligible for authorization under the revised third criterion if it has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEB-APR-STP-0059 within 45 calendar days of May 7, 2020, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent. Respirators with removal dates after May 7, 2020 are not eligible for the revised third criterion. A respirator that meets the revised third criterion, or any of the other eligibility criteria in the EUA, is authorized and will be added to Appendix A as an authorized respirator once FDA confirms the eligibility criteria are met. Results from NIOSH's testing are provided at: <https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html> (<https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>)

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Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
10/15/2020	HeiQ Materials AG	HVB-FFP2-01
06/06/2020	Fujian Kang Chen Daily Necessities Co, Ltd.	K0450, 57793
05/07/2020	AAB (China) Co., Ltd	KN95
05/07/2020	Anshun Health and Medical Technology Co., LTD	AKF2002
05/07/2020	Bei (Dong Shan) Protective Supplies Co., LTD	B707
05/07/2020	Changsha JNEYL Medical Equipment Co., Ltd	JN-9501
05/07/2020	Changzhou Wedream Medical Device Co., Ltd	KN95
05/07/2020	Chongqing China Nano Technology Co., Ltd	ZN8005
05/07/2020	Chongqing Zaisheng Technology Co., Ltd.	ZS-A950
05/07/2020	Chuzhou Qiao Dong Industrial Co., Ltd	Langie KN95 FFP2

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Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
05/07/2020	Creative Concepts Manufacturing Ltd	02669, KN95
05/07/2020	CTT CO. Ltd.	KN95
05/07/2020	Daddybaby Co. Ltd.	KN95 FFP2
05/07/2020	DongGuan HuaGang Communication Technology Co., Ltd	KN95-A; KN95-B
05/07/2020	Dongguan Leihuo Medical Device Co., LTD	CPFM-100, CPFM-101, LH-KN95
05/07/2020	Dongguan Xianda Medical Equipment Co., Ltd	KN95
05/07/2020	Foshan Nanhai Weijian Sanbang Protective Equipment Technology Co., Ltd	KN95 Model 9051A
05/07/2020	Fujian Pageone Garment Co., Ltd	KN95
05/07/2020	Guangdong Fei Fan MStar Technology Ltd	KN95
05/07/2020	Guangdong Kaper Protection Technology Co., Ltd	KP-K02 (N95)
05/07/2020	Guangzhou Aiyinmei Co., LTD	A&F KN95
05/07/2020	Guangzhou Sunjoy Auto Supplies Co., LTD	Earhook folding type K1-K100, Headband folding type K1-K100
05/07/2020	Guangzhou Yihere Medical Technology Development Co., Ltd	YH-MFK-B95, YH-MFK-Z95
05/07/2020	Guizhou Bocai Medical Device Co., Ltd.	Bocai KN95
05/07/2020	Henan Fengzhihuang Industrial Co., Ltd	HF/KN95-3
05/07/2020	Henan Youmaisi Health Technology Co. LTD	YMS-AN95
05/07/2020	Huizhou Huinuo Technology Co., LTD	HV-N White 9501B
05/07/2020	Huizhou Jiahe Cubic Technology Co., LTD	KN95
05/07/2020	Huizhou Lexuslance Technology Co. Ltd.	LK 003
05/07/2020	Improve Medical (Hunan) Co., Ltd.	PPDS Disposable Protective Respirator Strap Headband, PPDS Disposable Protective Respirator Ear Hook
05/07/2020	Jiangsu Weichuangli New Materials Co., Ltd.	WCL-0075
05/07/2020	Jiangxi Hornet Industrial Co. Ltd.	S-KN95
05/07/2020	Jiangxi Yifengyuan Biological Engineering Co., Ltd.	N95, KN95
05/07/2020	Jinan Vhold Co., LTD	VH-95
05/07/2020	Juntech (Jiaxing) Healthcare Materials Co. Ltd	KN95
05/07/2020	Panzhuhua Gangcheng Group Yasheng Industrial Co., Ltd.	KN95
05/07/2020	Qingdao Orphila Medical Technology Co. LTD.	OM-KN95-FFP2
05/07/2020	Qingyuan Leite Technology Development Co.	GV-0095A, GVHKN95

Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
05/07/2020	Shandong Daddy's Choice Health Science and Technology Co., Ltd	Purism KN95
05/07/2020	Shandong Huishoutang Pharmaceutical Co	KN95
05/07/2020	Shandong Shengquan New Material Co., Ltd	SNN70370B (Willow leaf form valveless)
05/07/2020	Shauguan Taijie Protection Technology Co. Ltd.	KN95
05/07/2020	Shenzhen Horb Technology Corp., Ltd	1.7.02.02.0001
05/07/2020	Shenzhen Missadola Technology Co., Ltd, dba 1AK Medical Supplies	2626-1 KN95
05/07/2020	Sunright Medical Technology (GuangDong) Co., LTD	KN95-C3
05/07/2020	Tianjin Benmo Medical Equipment Co., Ltd.	KN95
05/07/2020	Winner Medical Co. Ltd.	WN-N95FG
05/07/2020	Yiwu Henghao household products Co., Ltd	HH-KN95-001
05/07/2020	Yiwu Yifan Knitting Co. Ltd	KN95
05/07/2020	Zhangzhou Easepal Industrial Corp.	MASK-104
05/07/2020	Zhejiang Baiyi Intelligent Garment Co LTD	KN95
05/07/2020	Zhejiang Shengtai Baby Products Co Ltd	KN95
05/07/2020	Zhengzhou QBS New Material Co., LTD	KN95
05/07/2020	Zhengzhou Wanshenshan Healthcare PPE Co., Ltd.	KN95

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Umbrella EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) (Reissued June 6, 2020)

On March 24, 2020, the FDA issued an umbrella EUA for certain imported disposable filtering facepiece respirators (FFRs) that are not approved by the National Institute for Occupational Safety and Health (NIOSH) and that meet criteria as described in the EUA. Under this EUA, authorized respirators, which are listed in Exhibit 1, are authorized for use in healthcare settings by healthcare personnel when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

On March 28, 2020, to further address the shortage of disposable FFRs, the FDA determined it was necessary to reissue the March 24, 2020 letter in order to amend the Scope of Authorization to additionally authorize the use of authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

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The FDA continues to be vigilant and take prompt action on imported, non-NIOSH approved respirators to ensure health care personnel receive adequate protection. On June 6, 2020, the FDA again revised this EUA to revise the scope concerning the decontamination of respirators with exhalation valves, and also revised the Scope of Authorization with respect to which jurisdictions are included in the second criterion for eligibility, among other revisions.

- [EUA Letter of Authorization - Umbrella EUA Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators \(/media/136403/download\)](#) (Reissued 06/06/2020)
- [Exhibit 1: Authorized Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators \(Updated November 9, 2020\)](#)

Exhibit 1: Authorized Imported, Non-NIOSH Disposable Filtering Facepiece Respirators (FFR) (Updated November 9, 2020)

The table below includes a list of authorized non-NIOSH-approved disposable filtering facepiece respirators (FFRs) authorized under this Umbrella EUA (/media/136403/download) for emergency use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators \(https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html\)](https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html).

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Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
3M	8205	Japan	
3M	8822	South Korea	
3M	9320+	UK, Singapore, Turkey	
3M	9322+	UK, Singapore, Turkey	
Ap Mascarillas S.A. de C.V.	AP M10, AP Z6	Mexico	
Brands Unlimited S.A. de C.V.	Medimask MM-001	Mexico	
BTL Industries	FLAT-FIT Healthcare Respirator	Bulgaria	<ul style="list-style-type: none"> • IFU (https://btl-misc.s3.eu-west-1.amazonaws.com/misc/BTL_Respirator_LF_User-Manual_ENESUS100_preview.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dromex	Model 1020	South Africa	
Galia Textil S.A. DE C.V	GTN95	Mexico	<ul style="list-style-type: none"> • IFU (https://galiatextil.org/en/producto/n95-respirator-2/) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Grupo 10X SA DE CV d.b.a Sanitek Pro	Sanitek Pro N95	Mexico	<ul style="list-style-type: none"> • IFU (https://sanitekpro.com/n95-respirator/) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
Novita, 9 Koi Marketing Pte Ltd	R5	Singapore	<ul style="list-style-type: none"> IFU (http://novita.com.sg/web/userguide/index.html) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Plastcor Do Brasil LTDA	ECHO PFF2 CA 38.811	Brazil	<ul style="list-style-type: none"> IFU (http://plastcors.com/instructionsforuse.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Rose Personal Protective Equipment Industry and Trade Anonym Company	IRYS-08	Turkey	<ul style="list-style-type: none"> IFU (http://ivrou.com/pdf/Intended%20Use%20and%20Other%20Instructions%20of%20IVROU-revised.pdf) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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Face Shields and Other Barrier EUAs

On May 1, 2020, the FDA issued an umbrella EUA for emergency use of protective barrier enclosures by healthcare providers (HCP) when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment (PPE). The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

On August 20, 2020, based on FDA's continued review of the scientific evidence available, the FDA has become aware of information that supports a determination to revoke the umbrella EUA on the grounds that the criteria under section 564(c) of the Act for issuance of an EUA are no longer met (see section 564(g)(2)(B)). Under section 564(c) of the Act, an EUA may be issued only if FDA concludes "that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing ---(i) such disease or condition [...]; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product [...]." In addition, FDA has determined that revocation is appropriate to protect the public health or safety (see section 564(g)(2)(C) of the Act), and that individualized consideration of each EUA request for protective barrier enclosures would better protect the public health.

Face shields and other barriers are a type of PPE intended to protect the user from bodily fluids, liquid splashes, or potentially infectious materials. Availability of certain PPE are an integral part of routine patient care during the COVID-19 pandemic. The table below includes authorization information about the use of authorized face shields and other barriers for use during the COVID-19 public health emergency.

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Date	EUA	Issued	PPE (Letter of Authorization)	Other Documents
09/24/2020	COVIAGE (/media/142447/download)			<ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers (/media/142450/download) • Fact Sheet for Patients (/media/142451/download) • Instructions for Healthcare Facilities: Assembly, Disassembly, and Disinfection of COVIAGE (/media/142448/download) • Instructions for Healthcare Personnel (HCP): Use of COVIAGE (/media/142449/download)
07/24/2020	Airway Dome (/media/140455/download)			<ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers (/media/140452/download) • Fact Sheet for Patients (/media/140456/download) • Instructions for Healthcare Facilities: Assembly and Disposal of the Airway Dome (/media/140453/download) • Instructions for Healthcare Provider (HCP): Use of the Airway Dome (/media/140454/download)
06/13/2020	Negative-pressure Respiratory System with Advanced Ventilation Return (NRS AVR-100) (/media/138955/download)			<ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers (/media/138956/download) • Fact Sheet for Patients (/media/138957/download) • Instructions for Healthcare Facilities (/media/138958/download) • Instructions for Healthcare Personnel (/media/138959/download)
05/27/2020	Gowns and Other Apparel (/media/138326/download)			<ul style="list-style-type: none"> • None
05/19/2020	COVID-19 Airway Management Isolation Chamber (CAMIC) (/media/139391/download) (Reissued 06/22/2020)			<ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers (/media/139392/download) • Fact Sheet for Patients (/media/139393/download) • Instructions for Healthcare Facilities - Assembly, Disassembly and Disinfection of the CAMIC (/media/139394/download) • Instructions for Healthcare Personnel - Use of the CAMIC (/media/139395/download)
05/08/2020	Patient Isolation Transport Unit (PITU) Device (/media/137856/download)			<ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers (/media/137857/download) • Fact Sheet for Patients (/media/137858/download) • PITU Set Up and Operation Guide (/media/137859/download) • PITU User Manual (/media/137860/download)

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Date**EUA****Issued**

PPE (Letter of Authorization)



Other Documents



04/09/2020 Face Shields (/media/136842/download)

• None

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Additional Resources:

- N95 Respirators and Surgical Masks (Face Masks) (/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks)
- Enforcement Policy guidance webinar (/medical-devices/workshops-conferences-medical-devices/webinar-enforcement-policy-personal-protective-equipment-ppe-during-covid-19-immediately-effect)
- FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic)
- Face Masks and Surgical Masks for COVID-19: Manufacturing, Purchasing, Importing, and Donating Masks During the Public Health Emergency (/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during)



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