FDA COMBATING COVID-19 WITH MEDICAL DEVICES

Since the beginning of the COVID-19 pandemic, FDA has been working to facilitate the development and availability of medical products and equipment for use by patients, physicians and healthcare systems as expeditiously and safely as possible. All of FDA's latest actions around COVID-19 are available on our website.

During public health emergencies, FDA can use emergency authorities, including Emergency Use Authorizations (EUAs), to help make medical products available as quickly as possible by allowing unapproved medical products to reach patients in need when there are no adequate, FDA-approved and available alternatives. These products may include tests to help diagnose diseases, critical medical devices needed by patients or healthcare personnel in the context of a public health crisis, and drugs to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions.

During this pandemic, there have been a number of supply issues that have made it challenging to obtain access to diagnostic tests and test supplies (like swabs), and medical equipment. We are updating FAQs on our webpage regularly to provide information on diagnostic testing, including alternative test supplies and ways to conduct testing when necessary. If test developers or labs are having any issues developing or running tests, and for difficulties obtaining medical devices such as personal protective equipment (PPE) and other medical equipment shortages, we have a toll-free phone line, 1-888-INFO-FDA (1-888-463-6332), then press star (*), that is open Monday-Friday: 8:00 a.m.-midnight ET. Weekends and holidays: 8:00 a.m.-8:00 p.m. E.T.

Testing is one of the pillars of our nation's response to COVID-19 and the FDA continues to take actions to help make these critical products available, including by issuing EUAs. During this pandemic, FDA has issued EUAs to different types of COVID-19 tests. One type are polymerase chain reaction (PCR) tests, a molecular diagnostic testing technique that detects the genetic material from the virus and can help diagnose an active COVID-19 infection. Another type are serological tests that look for antibodies to the virus, which can help identify individuals who have developed an adaptive immune response to the virus, as part of either an active infection or a prior infection (serological, or antibody, tests should not be used to diagnose active infection). The newest type of authorized COVID-19 tests are antigen tests, designed for the rapid detection of proteins from the virus that causes COVID-19.

The molecular diagnostic tests are generally authorized for qualitative detection of nucleic acid from SARS-CoV-2 in specific upper and lower respiratory specimens from individuals suspected of COVID-19 by their healthcare provider. The specific specimen types for each test can be found in the authorization letter. Some molecular diagnostic tests may require a highly trained operator to manually perform the test (e.g., perform an RNA extraction step usually using specific extraction platforms and kits), while other tests are automated and require only limited training to perform). Typically, manually performed tests are authorized for use by laboratories certified to perform high-complexity tests, while automated tests are authorized for use by laboratories certified to perform moderate complexity tests and/or at the point-of-care by facilities operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver.

The serological (antibody) tests are generally authorized for the qualitative detection of antibodies to SARS-CoV-2 in blood, serum, and/or plasma, and are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The specific specimen types for each test can be found in the authorization letter.

Antigen tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. One of the main advantages of an antigen test is the speed of the test, which can provide results in minutes. However, antigen tests may not detect all active infections, as they do not work the same way as a PCR test. Antigen tests are very specific for the virus but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection.

In addition to COVID-19 tests, the FDA has issued EUAs for other devices, such as ventilators, respirators, face shields, decontamination systems and protective barrier enclosures to treat COVID-19 patients and to protect healthcare workers. The list below includes the device EUAs that FDA has issued to date to diagnose, treat and prevent the spread of COVID-19.

SPONSOR	PRODUCT (link to authorization letter)	DESCRIPTION
DIAGNOSTICS - ANTIGEN		
Quidel Corporation *5/08/2020*	Sofia 2 SARS Antigen FIA	• Can be run in moderate and high complexity labs and POC settings operating under a CLIA Certificate of Waiver
DIAGNOSTICS – MOLECULAR		
Center for Disease Control and Prevention *2/4/2020*	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	• Developed by CDC and initially distributed to public health labs across the country • Can only be run in high complexity labs
Wadsworth – New York State Public Health *2/29/2020*	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	• Developed by Wadsworth based on CDC's published protocol • Run in qualified labs across New York State • Can only be run in high complexity labs
Roche Molecular Systems, Inc. *3/12/2020*	cobas® SARS-CoV-2 for use on the cobas® 6800/8800 Systems	• Commercially distributed as a kit to labs • Can be run in moderate and high complexity labs
Life Technologies (a part of Thermo Fisher Scientific, Inc.) *3/13/2020*	TaqPath™ COVID-19 Combo Kit, 100 Rxn, TaqPath™ COVID-19 Combo Kit, 1,000 Rxn	• Commercially distributed as a kit to labs • Can only be run in high complexity labs
Hologic, Inc. *3/16/2020*	Panther Fusion SARS-CoV-2 Assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs

Quest Diagnostics Infectious Disease, Inc. *3/17/2020*	SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR	• Developed and run in Quest labs only; not a kit for distribution. • Can only be run in high complexity labs
Quidel Corporation *3/17/2020*	Lyra® SARS-CoV-2 Assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Abbott Molecular, Inc. *3/18/2020*	Abbott RealTime SARS-CoV-2 assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
GenMark Diagnostics, Inc. *3/19/2020*	ePlex SARS-CoV-2 Test	• Reagents commercially distributed as a kit to labs • Can run up to 24 specimens at the same time • Can be run in a moderate or high complexity lab
DiaSorin Molecular LLC *3/19/2020*	Simplexa COVID-19 Direct	• Reagents commercially distributed as a kit to labs • Can run 1 specimen at a time • Can be run in moderate and high complexity labs
Primerdesign Ltd. *3/20/2020*	Primerdesign Ltd COVID-19 genesig Real-Time PCR	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Cepheid *3/20/2020*	Xpert Xpress SARS-CoV-2 test	• Reagents commercially distributed as a kit to labs • Can run up to 2,000 samples per day • Can be run in a high or moderate complexity lab or at the Point of Care (POC) near the patient (deemed CLIA waived)
Mesa Biotech Inc *3/23/2020*	Accula SARS-CoV-2 Test	• Reagents commercially distributed as a kit to labs • Runs one specimen at a time • Can be run in a high or moderate complexity lab or at the Point of Care (POC) near the patient (deemed CLIA waived)
BioFire Defense, LLC *3/23/2020*	BioFire COVID-19 Test	• Reagents commercially distributed as a kit to labs • Can run up to 264 tests per day • Can be run in moderate or high complexity labs
PerkinElmer, Inc. *3/24/2020*	PerkinElmer New Coronavirus Nucleic Acid Detection kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Avellino Labs USA	AvellinoCoV2 test	• Developed and run in Avellino labs; not distributed to other labs

3/25/2020		• High complexity test limited to authorized laboratories
BGI Genomics Co. Ltd. *3/26/2020*	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Luminex Molecular Diagnostics, Inc. *3/27/2020*	NxTAG CoV Extended Panel Assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Abbott Diagnostics Scarborough, Inc. *3/27/2020*	ID NOW™ COVID-19	• Reagents commercially distributed as a kit • Requires a specific platform (ID NOW), of which there are 18,000 installed across the US • Runs one specimen at a time; each takes <13 minutes • Can be run in a high or moderate complexity lab or at the Point of Care (POC) near the patient (deemed CLIA waived)
NeuMoDx Molecular, Inc. *3/30/2020*	NeuMoDx SARS-CoV-2 Assay	• Reagents commercially distributed as a kit • Can run 288 or 96 samples at once, depending on the instrument, and takes 80 minutes per sample • Can be run in high and moderate complexity labs
QIAGEN GmbH *3/30/2020*	QIAstat-Dx Respiratory SARS-CoV-2 Panel	• Detects multiple other respiratory viral (17) and bacterial (3) organisms • Reagents commercially distributed as a kit to labs • Runs one specimen at a time and takes one hour • Can be run in high and moderate complexity labs
EUA for COVID-19 LDTs *3/31/2020*	Laboratory developed tests that are authorized are listed below and hyper link to letter granting inclusion under EUA	• Authorizes the use of LDTs that meet certain criteria • Authorized tests can be used in the high complexity CLIA-certified lab that developed the test
Laboratories (Date of Authorization) • AIT Laboratories (4/24/2020) • Altru Diagnostics (4/30/2020) • Biocerna (4/28/2020) • Biocollections Worldwide, Inc. (5/07/2020) • Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine **(5/13/2020)**		

• CirrusDx SARS-CoV-2 Assay (4/15/2020) • Columbia University Laboratory of Personalized Genomic Medicine **(5/12/2020)** • Diagnostic Molecular Laboratory-Northwestern Medicine (4/02/2020) • Diatherix Eurofins Laboratory (4/22/2020) • Exact Sciences Laboratories (4/14/2020) • Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory **(4/15/2020)** • Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital **(4/14/2020)** • Infectious Disease Diagnostics Laboratory-Children's Hospital of Philadelphia (4/02/2020) • Integrity Laboratories (4/13/2020) • Massachusetts General Hospital (Mass Gen) (4/03/2020) • Mayo Clinic Laboratories, Rochester, MN (04/20/2020) • Nationwide Children's Hospital (4/27/2020) • One Health Laboratories (5/13/2020) • Orig3n, Inc.(4/10/2020) • Pathology/Laboratory Medicine Lab of Baptist Hospital Miami (4/13/2020) • Southwest Regional PCR Laboratory LLC. PCR MicroGen DX (4/23/2020) • Specialty Diagnostic (SDI) Laboratories (4/10/2020) • Stanford Health Care Clinical Virology Laboratory (4/08/2020) • Ultimate Dx Laboratory (4/24/2020) • University of North Carolina Medical Center (4/10/2020) • UTMG Pathology Laboratory (5/01/2020) • Viracor Eurofins Clinical Diagnostics (4/06/2020) • Yale New Havel Hospital, Clinical Virology Laboratory (3/31/2020)		
Ipsum Diagnostics *4/1/2020*	COV-19 IDx Assay	• Uses commercially available reagents • Can only be run in high complexity labs by Ipsum
Becton, Dickinson & Company (BD) *4/2/2020*	BioGX SARS-CoV-2 Reagents for BD MAX System	• Reagents commercially distributed as a kit to labs • Fully automated, 8 samples per hour • Can be run in moderate and high complexity labs
Luminex Corporation *4/3/2020*	ARIES SARS-CoV-2 Assay	• Reagents commercially distributed as a kit to labs • Can be run in moderate and high complexity labs
ScienCell Research Laboratories *4/3/2020*	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Co-Diagnostics, Inc. *4/3/2020*	Logix Smart Coronavirus Disease 2019 (COVID-19) kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Gnomegen LLC *4/6/2020*	Gnomegen COVID-19 RT-Digital PCR Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs

InBios International, Inc *4/7/2020*	Smart Detect SARS-CoV-2 rRT-PCR Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
DiaCarta, Inc. *4/8/2020*	QuantiVirus SARS-CoV-2 Test kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Becton, Dickinson & Company (BD) *4/8/2020*	BD SARS-CoV Reagents for BD MAX System	• Reagents commercially distributed as a kit to labs • Can be run in moderate and high complexity labs
Atila BioSystems, Inc. *4/10/2020*	iAMP COVID-19 Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs

Maccura Biotechnology (USA) LLC *4/15/2020*	SARS-CoV-2 Fluorescent PCR Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
GenoSensor, LLC. *4/16/2020*	GS™ COVID-19 RT-PCR KIT	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
KorvaLabs Inc. *4/16/2020*	Curative-Korva SARS-Cov-2 Assay	• Laboratory Developed Test • High complexity test limited to KorvaLabs, Inc., a certified high complexity laboratory
Fosum Pharma USA Inc. *4/17/2020*	Fosun COVID-19 RT-PCR Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
OSANG Healthcare *4/18/2020*	GeneFinder COVID-19 Plus RealAmp Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Trax Management Services Inc. *4/20/2020*	PhoenixDx 2019-CoV	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Seegene, Inc. *4/21/2020*	Allplex 2019-nCoV Assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
altona Diagnostics GmbH *4/22/2020*	RealStar SARS-CoV02 RT-PCR Kits U.S.	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
SD Biosensor, Inc. *4/23/2020*	STANDARD M nCoV Real-Time Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
SEASUN BIOMATERIALS *4/27/2020*	U-TOP COVID-19 Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Rheonix, Inc. *4/29/2020*	Rheonix COVID-19 MDxAssay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
LabGenomics Co., Ltd. *4/29/2020*	**LabGunCOVID-19 RT-PCR Kit**	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Bio-Rad Laboratories, Inc. *5/1/2020*	Bio-Rad SARS-CoV-2 ddPCR Test	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
BioFire Diagnostics, LLC *5/1/2020*	BioFire Respiratory Panel 2.1 (RP2.1)	• Reagents commercially distributed as a kit to labs • Can be run in high complexity labs

Sansure BioTech Inc. *5/4/2020*	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company) *5/5/2020*	FTD SARS-CoV-2	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Sherlock Biosciences, Inc. *5/6/2020*	Sherlock CRISPR SARS-CoV-2 Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
OPTI Medical Systems, Inc. *5/6/2020*	OPTI SARS-CoV-2 RT PCR Test	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
BioMérieux SA *5/6/2020*	SARS-COV-2 R-GENE	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Zymo Research Corporation *5/7/2020*	Quick SARS-CoV-2rRT-PCR Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Gnomegen LLC *5/8/2020*	Gnomegen COVID-19-RT-qPCR Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Abbott Molecular Inc. *5/11/2020*	Alinity m SARS-CoV-2 assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
1drop Inc. *5/11/2020*	1copy COVID-19 qPCR Multi Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Applied DNA Sciences, Inc. *5/13/2020*	Linea COVID-19 Assay Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
GeneMatrix, Inc. *5/14/2020*	NeoPlex COVID-19 Detection Kit	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Hologic, Inc. *5/14/2020*	Aptima SARS-CoV-2 assay	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
Quidel Corporation *5/18/2020*	**Lyra Direct SARS-CoV-2 Assay**	• Reagents commercially distributed as a kit to labs • Can only be run in high complexity labs
DIAGNOSTICS – MOLECULAR – HOME COLLECTION		

Can be used with specimens that are self-collected at home with specific collection kits, then sent to the lab for testing.		
Laboratory Corporation of America *3/16/2020* *Amended 4/ 20/2020*	COVID-19 RT-PCR Test COVID-19 RT-PCR Amendment	• Developed and run in high complexity LabCorp labs only; not for broader lab distribution • *Amendment permits use of the Pixel by LabCorp COVID-19 test home collection kit allowing patients to self-collect nasal swab specimens at home* • *The kit provides specimen collection materials and materials to safely mail specimens to an authorized laboratory*

Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University *5/7/2020*	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay	• First diagnostic test using at-home collection of saliva specimens
Everlywell, Inc. *5/15/2020*	Everlywell COVID-19 Test Home Collection Kit	• For use by individuals to self-collect nasal swab specimens at home, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire, and for use only with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with the Everlywell COVID-19 Home Collection Kit.
Assurances Scientific Laboratories *5/15/2020*	Assurance SARS-CoV-2 Panel	• Laboratory developed test, limited to Assurance Scientific high complexity lab • Can be used with nasal swab specimens that are self-collected at home with the Everlywell home collection kit, then sent to the lab for testing.
Fulgent Therapeutics, LLC. *5/15/2020*	Fulgent COVID-19 by RT-PCR Test	• Laboratory developed test, limited to Fulgent Therapeutics high complexity lab • Can be used with nasal swab specimens that are self-collected at home with the Everlywell home collection kit, then sent to the lab for testing.
SEROLOGY/ANTIBODY TESTS		
Cellex Inc. *4/1/2020*	Serology Test qSARS-CoV-2 IgG/IgM Rapid Test	• The first serological test authorized under EUA. • Detects SARS-CoV-2 antibodies in blood and differentiates between IgG and IgM antibodies. • Rapid test provides results in 15-20 minutes. • Can be run in high and moderate complexity labs
Chembio Diagnostic Systems, Inc. *4/14/2020*	DPP COVID-19 IgM/IgG System	• Detects and differentiates IgM and IgG antibodies in whole blood, fingerstick whole blood, serum and plasma. • Can be run in high and moderate complexity labs
Ortho-Clinical Diagnostics, Inc. *4/14/2020*	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	• Detects IgG antibodies in serum. • Can be run in high and moderate complexity labs

Mount Sinai Laboratory *4/15/2020*	COVID-19 ELISA IgG Antibody Test	• Detects IgG antibodies in serum and plasma. • Test is limited to Mount Sinai Laboratory.
DiaSorin Inc. *4/24/2020*	LIAISON SARS-CoV-2 S1/S2 IgG	• Detects IgG antibodies in serum and plasma. • Can be run in high and moderate complexity labs
Autobio Diagnostics Co. Ltd. *4/24/2020*	Anti-SARS-CoV-2 Rapid Test	• Detects and differentiates IgM and IgG antibodies in serum and plasma • Can be run in high and moderate complexity labs
Ortho Clinical Diagnostics, Inc. 4/24/2020	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	• Detects and differentiates IgM and IgG antibodies in serum and plasma • Can be run in high and moderate complexity labs
Abbott Laboratories Inc. *4/26/2020*	SARS-CoV-2 IgG assay	• Detects IgG antibodies in serum and plasma. • Can be run in high and moderate complexity labs
Manufacturers of In vitro diagnostic SARS-CoV-2 Antibody Tests that have been evaluated in an independent validation study performed by NIH National Cancer Institute or by another government agency designated by FDA and confirmed by FDA to meet the criteria set forth in the Scope of Authorization *4/28/2020*	FDA issued an Emergency Use Authorization for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by FDA, and are confirmed by FDA to meet the criteria set forth in the Scope of Authorization (Section II) in the Letter of Authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized devices are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies (IgG, or IgG and IgM, or total), as specified in each authorized device's instructions for use, to SARS-CoV-2 in human plasma and/or serum. Emergency use of the authorized devices is limited to the authorized laboratories. Authorized Laboratories are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests. Authorized devices will be added to Appendix A (below) upon submission of the information set forth in the Scope of Authorization (Section II) and after confirmation that the applicable performance and labeling criteria set forth in the Scope of Authorization (Section II) have been met. • Fact Sheet for Healthcare Providers • Fact Sheet for Recipients • Appendix A Table	

Bio-Rad Laboratories *4/29/2020*	Platelia SARS-CoV-2 Total Ab assay	• Detects and differentiates IgM and IgG antibodies in serum and plasma • Can be run in high complexity labs
Wadsworth Center, New York State Department of Health *4/30/2020*	New York SARS-CoV Microsphere Immunoassay for Antibody Detection	• Detects total antibodies in serum. • Test is limited to Wadsworth Center, New York State Department of Health.
Roche Diagnostics *5/2/2020*	Elecsys Anti-SARS-CoV-2	• Detects Anti-SARS-Cov-2 antibodies in serum and plasma. • Can be run in moderate and high complexity labs
EUROIMMUN US Inc. *5/4/2020*	Anti-SARS-CoV-2 ELISA (IgG)	• Detects IgG antibodies in serum and plasma. • Can be run in high complexity labs
DEVICES		
Advanced Sterilization Products, Inc. *4/15/2020*	Advanced Sterilization Products (ASP) STERRAD Sterilization System	Decontaminates compatible N95 or N95-equivalent respirators for single user reuse by healthcare personnel to prevent exposure to airborne particulates when there are insufficient supplies of N95 respirators.
ALung Technologies, Inc., *4/22/2020*	Hemolung Respiratory Assist System (RAS)	Intended to treat lung failure caused by COVID-19 when used as an adjunct to noninvasive or invasive mechanical ventilation to reduce hypercapnia and hypercapnic acidosis, and/or to maintain normalized levels of partial pressure of carbon dioxide (PCO2) and pH in patients suffering from acute, reversible respiratory failure for whom ventilation of CO2 cannot be adequately, safely, or tolerably achieved.
Ascorn (US), Inc. *5/11/2020*	Ascorn teleCARE IP Nurse Call System	A nurse call system for use by healthcare providers and patients in healthcare environments, including temporary hospital facilities, as a powered environmental control system intended for medical purposes with additional hardware and software modifications implementing the capability for remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider.
Battelle	Battelle Decontamination System	A single compatible respirator to be recycled and reused up to 20 times using the Battelle Decontamination System

3/29/2020		Battelle is authorized to scale up their operations to decontaminate about 120,000 respirators daily by using all 12 of their satellite facilities once they submit data to FDA
Baxter Healthcare Corporation *4/22/2020*	oXiris Set device	The oXiris Set device is an extracorporeal blood purification device used to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy, to reduce pro-inflammatory cytokines levels
B.Braun *4/11/2020*	Space and Outlook Pumps (Infusion Pump)	An infusion pump for delivery of medications into a nebulizer to treat COVID-19 patients of all ages
Comunale *5/08/2020*	Patient Isolation Transport Unit (PITU) Device	The PITU is for temporary isolation and transport of patients by providing an extra layer of barrier protection in addition to personal protective equipment (PPE).
CytoSorbents, Inc. *4/10/2020*	CytoSorb Device (Extracorporeal Blood Purification (EBP) Device)	Blood purification system to treat patients 18 years older with confirmed COVID-19 diagnosis admitted to the intensive care unit with confirmed or imminent respiratory failure
Duke University Health System *5/7/2020*	Duke Decontamination System	Decontaminates compatible N95 or N95 equivalent respirators
ExThera Medical Corporation *4/17/2020*	Seraph 100 Microbind Affinity Blood Filter Device	Blood purification system to treat patients 18 years older with confirmed COVID-19 diagnosis admitted to the intensive care unit with confirmed or imminent respiratory failure
Eko Devices, Inc. *5/11/2020*	LVEF Screen	Allows for emergency use of the Eko electrocardiogram (ECG) Low Ejection Fraction Tool ("ELEFT") to be used by healthcare professionals to provide an assessment of Left Ventricular Ejection Fraction (LVEF) for use as a diagnostic to screen for potential cardiac complications associated with COVID-19 or underlying cardiac condition that may affect clinical management of COVID-19, in adult patients having or suspected of having COVID-19.
Fresenius Medical 4/30/2020	multiFiltrate PRO System and multiBic/multiPlus Solutions	Provides continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic.
G Medical Innovations, Ltd.	G Medical VSMS ECG Patch	Allowed for use by healthcare professionals in the hospital setting for remote monitoring of the QT

5/14/2020		interval of an electrocardiogram (ECG) in general care who are 18 years of age or older and are undergoing treatment for COVID-19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias.
Liberate Medical, LLC *5/1/2020*	VentFree Respiratory Muscle Stimulator Device	It is intended to be used by healthcare professionals (HCP) in healthcare settings to reduce disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in adult patients who require mechanical ventilation.
Lungpacer Medical, Inc. *4/14/2020*	Lungpacer Medical, Inc. Diaphragm Pacing Therapy System (DPTS)	A device that assists in weaning patients that are at risk of weaning failure off breathing assistance machines requiring patient intubation
Philips Medizin Systeme Boeblingen GmbH *4/21/2020*	IntelliVue Patient Monitors MX750/MX850, IntelliVue 4-Slot Module Rack FMX-4, and IntelliVue Active Displays AD75/AD85 Collectively Referred to as "IntelliVue Patient Monitors"	Remote patient monitoring for healthcare professionals in the hospital environment for remote monitoring of adult, pediatric, and neonate patients having or suspected of having COVID-19 to reduce healthcare provider exposure to COVID-19
PhysiolGuard Corporation Ltd. *5/05/2020*	PhysiolGuard, ECQ-QT Analysis System	Remote patient monitoring for healthcare professionals in the hospital setting for remote monitoring and detection of changes in the QT interval of an ECG
Sterilucent, Inc. *4/20/2020*	Sterilucent, Inc. Sterilization System	Decontaminates compatible N95 or N95 equivalent respirators (compatible N95 respirators) for single-user reuse by healthcare personnel
STERIS *4/09/2020*	STERIS V-PRO 1 Plus, maX, and maX2 Lower Temperature Systems (STERIS Sterilization Systems)	Decontaminates compatible N95 or N95 equivalent respirators (compatible N95 respirators) for single-user reuse by healthcare personnel
Stryker *4/15/2020*	STERIZONE VP4 N95 Respirator Decontamination Cycle	Decontaminates compatible N95 or N95 equivalent respirators (compatible N95 respirators) for single-user reuse by healthcare personnel
Synapse Biomedical, Inc. *4/13/2020*	Synapse Biomedical, Inc. TransAeris Diaphragmatic Pacing Therapy System (DPTS)	A device that assists in weaning patients that are at risk of weaning failure off breathing assistance machines.
Terumo BCT Inc. and Market Therapeutics AG	Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge	Blood purification system to treat patients 18 years older with confirmed COVID-19 diagnosis

4/09/2020		admitted to the intensive care unite with confirmed or imminent respiratory failure
VitalConnect, Inc. *4/26/2020*	VitalConnect, Inc., VitalPatch	Remote monitoring system used for monitoring and detection of changes in the QT interval of an electrocardiogram (ECG) in adult (>18) patients in general care (not in the intensive care unit) and are undergoing treatment with COVID-19 drugs that may cause life threatening arrhythmias.
Walter Reed National Military Medical Center *5/19/2020*	**COVID-19 Airway Management Isolation Chamber (CAMIC)**	**Emergency use of the CAMIC within the U.S. Army and MHS by healthcare providers as an extra layer of barrier protection in addition to personal protective equipment to exposure to pathogenic biological airborne particulates during transport of suspected or confirmed COVID-19 patients at the time of definitive airway management, or when performing medical procedures on patients during COVID-19.**
Manufacturers of Face Masks (non-surgical) *4/18/2020*	Face masks are authorized under this umbrella authorization when they are intended for use by **members of the general public, which includes HCP (refers to all paid and unpaid persons serving in healthcare settings),** to cover their noses and mouths in accordance with CDC recommendations. Authorized face masks must meet the following requirements: 1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics); 2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection, and includes recommendations that would reduce the risk of such use; for example, the labeling might include recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; or as an alternative example, recommendations for use only by the general public; and 3. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling should not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction, nor should it be used for particulate filtration. For conditions of authorization for manufacturers and distributors, including conditions related to advertising and promotion, see pages 4-6 of Letter of Authorization.	
Manufacturers of Face Shields	Face shields for use by HCP as PPE are authorized under this EUA when they are intended for use by HCP as PPE in healthcare settings in accordance with CDC	

4/09/2020	recommendations to cover the front and sides of the face and provide barrier protection and meet the following requirements: A. The product is labeled accurately to describe the product as a face shield for medical purposes and includes a list of the body contacting materials (which does not include any drugs or biologics); B. The product is not integrated with any other article of PPE such as a face mask, but rather is for use as a standalone face shield. C. The product includes labeling that describes the product as intended for either a single-user, single use, or for multiple uses by the same user, and includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable. D. The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas); E. The product is not intended for any use that would create an undue risk in light of the public health emergency; for example, the labeling does not state that use of the authorized face shield alone will prevent infection from microbes or viruses, or that it is effective against radiation protection. As indicated in Section I, face shields authorized by this EUA may be effective at preventing HCP exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19. All manufacturers are reminded that they must comply with all Conditions of Authorization, including those relating to advertising and promotion in Section IV of this letter. Manufacturers of authorized face shields do not need to take any action, other than complying with the Conditions of Authorization (Section IV) in this letter of authorization to be an authorized face shield under this EUA if they are within the Scope of Authorization (Section II) of this EUA.
Manufacturers of Protective Barrier Enclosures	Currently, there are no FDA-cleared or approved barrier protection devices that are available for use by HCPs 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. A protective barrier enclosure is a transparent device designed to cover a patient's head and upper body that incorporates one or more ports through which the HCP's hands are passed to perform medical procedures. Protective barrier enclosures are authorized under this EUA when they are intended for use by HCPs 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 PPE and meet the following requirements: 1. The product is labeled accurately to describe the product as a protective barrier enclosure that provides an extra layer of barrier protection in addition to PPE and includes a list of the body contacting materials (which does not include any drugs, biologics, antimicrobial agents, or nanoparticles).

5/01/2020	2. The product includes labeling that clearly states that the product is not intended to replace PPE. 3. The product includes labeling that clearly describes the instructions for use, including instructions for the HCP to assess patient status prior to device use, instructions on removal of the product if it impedes patient care or communication, and specific precautions for the use on certain patients. 4. The product must be made with transparent materials to provide a clear, unobstructed view of the procedure field. 5. The product does not include fans, air filters, or other features and is not intended to generate negative pressure. 6. The product includes labeling that describes the product as intended for either single use or for multiple uses; if a protective barrier enclosure is intended for multiple uses, the device labeling must include instructions for recommended thorough cleaning and response with an additional layer of barrier protection may be helpful in order to reduce the risk of transmission of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19. Page 4 - Protective Barrier Enclosures disinfection methods using a compatible EPA-registered hospital disinfectant from the EPA *List N: Disinfectants for use against CoV-2.* 7. The product does not contain or combine any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas). 8. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling should not state or imply that the authorized product is intended for any other medical purposes, such as airway management, the labeling should not state or imply that use of the authorized product alone will prevent infection from or transmission of microbes or viruses, or that it is effective protection against radiation. 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 healthcare providers and patients: • Fact Sheet for Healthcare Personnel • Fact Sheet for Patients	
RESPIRATORS		
CDC *4/3/2020*	National Institute for Occupational Safety and Health (NIOSH)-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency	Decontaminates compatible N95 or N95-equivalent respirators for single user reuse by healthcare personnel to prevent exposure to airborne particulates when there are insufficient supplies of N95 respirators.
• Non-powered air-purifying particulate Filtering facepiece respirators (FFRs) and reusable respirators such as elastomeric half and full faced facepiece respirators, approved by NIOSH and listed on the NIOSH Certified Equipment list (CEL) for non-powered air purifying respirators with particulate protection;		

• Other powered air purifying respirators (PAPRs) approved by NIOSH, and that are listed on the NIOSH CEL for PAPRs with particulate protection; • FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles; and, • Any authorized respirator that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system.		
Manufacturers and other Stakeholders – Certain Imported Filtering Facepiece Respirators *3/28/2020*	Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators • Products from the following countries: Australia, Brazil, Europe, Japan, South Korea, and Mexico; and/or • Products authorized in the following regulatory jurisdictions: European CE Mark, Australia Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada License, or Japan Pharmaceuticals and Medical Device (PMDA)/Ministry of Health and Labour and Welfare (MHLW)	This EUA authorizes certain respirators, including ones that have used a specific decontamination system, to be used in health care settings by healthcare personnel in accordance with CDC's recommendations. Authorized Respirators are listed in Exhibit 1 and listed below.
Authorized Imported, Non-NIOSH Approved Respirators • 3M, Model 8205, Manufactured in Japan • 3M, Model 8822, Manufactured in South Korea • 3M, Model 9320+, Manufactured in UK, Singapore, Turkey • 3M, Model 9322+, Manufactured in UK, Singapore, Turkey • Dromex, Model 1020, Manufactured in South Africa		
Manufacturers of Imported, Non-NIOSH-Approved Disposable Respirators Made in China and other Stakeholders	Imported, Non-NIOSH-Approved Disposable Respirators Made in China	This EUA allows disposable non-NIOSH-approved respirators manufactured in China that meet one of the following criteria to be eligible for authorization after completing a verification process: 1. Manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be

4/3/2020 *Amended 5/07/2020*		verified by 8 FDA; or, 2. It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA; or The EUA also authorizes respirators listed in Appendix A (also listed below) that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China
Manufacturer, Model, Location of Manufacturing

- 3M, 9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V, Made in China.
- AOK Tooling Ltd. (aka Shenzhonghai Medical), 20130040, 20130045A, 20180021, 20130038, 20190019, Made in China.
- Bei Bei Safety Co Ltd., B702, B702V, B704, B704V, Made in China.
- BYD Precision Manufacture Co. Ltd., BYD KN95 Particulate Respirator (Model Number DG3101), Made in China.
- Fujian Kang Chen, Daily Necessities Co, Ltd., K0450, 57793, Made in China.
- Guangzhou Harley Commodity Company Limited, L-103V, KN95, Made in China.
- Guangzhou Powecom Labor Insurance Supplies Co., LTD. KN95, Made in China.
- HeiQ Materials AG, HVP-FFP2-01, Made in China.
- Hangzhou San Qiang Safety Protection Products Co., Ltd. 9420 (FFP2), 9420V (FFP2), 9480 (FFP2), 9480V (FFP2), 9980V (FFP3), 9920V (FFP3), Made in China.
- Rizhao Saniqi Medical & Health Articles Co., Ltd. RIZ100CVb, 3Q KN95, 3Q FFP2 NR, RIZQ100Sb, 3Q KN95 9505, Made in China.
- Shanghai Dasheng Health Products Manufacture Company, Ltd., DTC3X-1, DTC3C-2, DTC3X-3, DTC3B-1, Made in China.
- Suzhou Bolisi Medical Technology Co., Ltd., BS-9501L, BS-9501FL, BS-9502C, BS-9502FC, Made in China.
- Suzhou Sanical Protective Product Manufacturing Co., Ltd., Model 8015, Model 9015. Made in China.
- Weini Technology Development Co., Ltd. FFP2 NR E-300, FFP NR E-680, FFP2 NR 952, FFP2 NR F-820, Made in China.

VENTILATORS

Manufacturers and other stakeholders	Eligible products are new/modified ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"),	Authorizes the use of these products if they meet specific criteria for safety performance, and labeling, (listed in Appendix B) and available here and listed below:

3/24/2020	ventilator tubing connectors, and ventilator accessories.	

Authorized Ventilators:
Manufacturer, Product Name, *(Date of Authorization)*
Device *Description/Intended Use*

- Beijing Aeonmed Co, Ltd. VG70 ventilator (*3/25/2020)*
  Critical care ventilators for mechanical ventilation of patients in ICU
- Shenzen Mindray Biomedical Electronics, Mindray SV300/SV600/S800 ventilators (*3/28/2020)*
  Critical care ventilator intended to provide ventilation assistance and breaking support for adult, pediatric and infant patients
- Vyaire Medical Inc. LTV2 model 2150 (*3/28/2020)*
  Critical care ventilator that are intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation
- RESMED, Stellar 150 *(3/30/2020)*
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use. The Stellar 150 is intended to provide ventilation for non-dependent spontaneously breathing adult and pediatric patients (30 lb/13 kg and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnea. The device is for invasive use (with the use of the ResMed Leak Valve)
- RESMED, Lumis 150 VPAP ST *(3/30/2020 Amended 4/17/2020)*
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use. The ResMed Lumis 150 VPAP ST devices are indicated to provide non-invasive ventilation for patients weighing more than 30 lbs (13 kg), or more than 66 lbs (30kg) in iVAPS mode, with respiratory insufficiency or obstructive sleep apnea (OSA). They are intended for home and hospital use
- RESMED, GA ST *(3/31/2020)*
  Ventilator, Continuous, Minimal Ventilatory Support for patients weighing more than 44lbs., Facility Use
- RESMED, Flexo Bi Level ST *(3/31/2020)*
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use
- RESMED, AirCurve ST *(3/31/2020 Amended 4/17/2020)*
  Ventilatory, Continuous, Minimal Ventilatory Support for patients weighing more than 66lbs, Facility Use
- Amsino, YUWELL YH-730 Bi-level PAP and YH-830 Bi-level Pap *(3/31/2020)*
  Ventilator for patients weighing more than 66lbs, Non-Continuous
- Inovytec, Ventway Sparrow *(3/31/2020)*
  Ventilator, Continuous for pediatric and adult patients
- Philips Respironics, VX850 Ventilator *(4/1/2020)*
  Critical Care Ventilator for pediatric (infants) and adults
- BMC Medical CO. LTD. Luna G3 BPAP 25A-LG3700 *(4/2/2020)*
  Ventilator, continuous, minimal ventilatory support for adult use, facility use
- BMC Medical CO. LTD. Y-30 T *(4/2/2020)*
  Ventilator, continuous, minimal ventilatory support for adult patients, facility use
- Dragerwerk AG & CO. KGaA, Evita V800 and Evita V600 *(4/2/2020)*
  Critical Care Ventilator for adults, adolescents, children, infants and neonates
- Dragerwerk AG & CO. KGaA, Babylog VN800 and VN600. *(4/3/2020)*
  Critical Care Ventilator intended for neonates and pediatric patients
- GE Healthcare, pNeuton Model, A-E Ventilator *(4/3/2020)*

Ventilator, Continuous, Facility Use

- Covidien LLC, Puritan Bennett 560 Ventilator System *(4/5/2020)*
  Ventilator, Continuous for adult and pediatric patients
- CoLabs. COVID Ventilator *(4/6/2020)*
  Emergency Ventilator for adult patients
- MEKICS Co., Ltd., MTV1000 Ventilator *(4/6/2020)*
  Ventilator, Continuous for use on pediatric and adult patients
- Dragerwerk AG & Co. KGaA, Atlan A350 and Atlan A350XL *(4/7/2020)*
  Gas-Machine, Anesthesia intended for anesthetizing adults, pediatric patients and neonates
- VenTec Life Systems, V+Pro Emergency Ventilator *(4/7/2020)*
  Ventilator for pediatric and adult patients, continuous
- Ambulancetech Co., Ltd. Models 6000S, T5, T7 *(4/8/2020)*
  Emergency transport ventilator, children and adults
- Philips Respironics, E30 ventilator
  Ventilator, Continuous, Minimal Ventilatory Support, facility use
- Incoba, LLC., Apogee *(4/8/2020)*
  Oxygen Conserver intended as a delivery device for medical grade oxygen from high-pressure oxygen cylinders. Ambulatory device for use in hospital, healthcare facilities, or home care environments.
- SecondBreath LLC, Pneumatic Resuscitator device *(4/13/2020)*
  Emergency Resuscitator
- University of Minnesota Medical School and Boston Scientific Corporation, Coventor Adult Manual Resuscitator Compressor *(4/14/2020)*
  Emergency Resuscitator
- Umbulizer, UMV-001 EUA *(4/14/2020)*
  Emergency Resuscitator
- Hillrom, MetaNeb 4 *(4/16/2020)*
  Intermittent Positive Pressure Breathing Device for patients 5 years old and above whom can follow verbal instructions in hospitals, subacute and nursing facilities, physician offices, clinics and home settings.
- Spiro Devices, LLC. Spiro Wave *(4/17/2020)*
  Emergency Resuscitator to support adults when Positive Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure
- RESMED. AirCurve 10 ST-A *(4/17/2020)*
  Ventilator, Continuous, minimal ventilatory support for facility use in patients weighting more than 30lbs
- PVA, PREVENT *(4/17/2020)*
  Emergency Resuscitator for emergency resuscitation with appropriate critical care monitoring on adult patients weighing more than 66 lbs
- 3B Medical Inc. Luna G3 B30VT *(4/20/2020)*
  Ventilator, Continuous Minimal Ventilatory Support
- Resvent, iBreeze PAP *(4/20/2020)*
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use
- Virgin Orbit, Virgin Orbit Resuscitator *(4/22/2020 Amended 4/23/2020)*
  Emergency Resuscitator
- Amisino International Inc's, YUWELL YH-725 *(4/23/2020)*
  Ventilator, Non-Continuous

- AutoMedX Inc., SAVe II Series Ventilator *(4/24/2020)*
  Powered emergency Ventilator
- SLS Medical Technology Corp. Ltd., CP101/CP101S Series *(4/24/2020)*
  Ventilator, Non-Continuous
- Zhehiang LifeMed Technology Co., Ltd., LA Series Ventilators LA20C, LA20A, LA20B, LA25B *(4/24/2020)*
  Ventilator, Non-Continuous
- Resvent Medical Technology CO., Ltd's, iBreeze 20STA device *(4/27/2020)*
  Ventilator, Non-Continuous
- Shenzhen Yamind Medical Tech, CPAP Devices: DM28-20C-G; Auto CPAP Devices: DM28-20A-W, DM28-20A-WP; BiPAP Devices: DM28-20S-G, DM28-20SA-G, DM28-20ST-G, DM28-25S-B, DM28-25SA-BP, DM28-25ST-BP, DM28-30ST-B, DM28-30ST-BP, DM28-30STA-BP *(4/28/20)*
  Ventilator, Non-Continuous
- NASA Jet Propulsion Laboratory, VITAL Ventilator *(4/30/2020)*
  Emergency ventilator
- Venti-Now, Venti-Now Resuscitator Model JM-P2020A *(4/30/2020)*
  Emergency Resuscitator
- Wilcox Industries Corp., Wilcox PATRIOT SAVR *(5/1/2020)*
  Emergency Ventilator
- Elamaster S.p.A. Techolgie Elettroiche, Mechanical Ventilator *(5/1/2020)*
  Emergency Ventilator
- BMC Medical CO., LTD., China., Luna G3 BPAP S/T-LG3800-G3 B30VT *(5/2/2020)*
  Ventilator, Continuous, Minimal Ventilatory Support
- ZIBO ZHONGXUN MEDICAL EQUIPMENT CO. LTD., ZXH-550 *(5/2/2020)*
  Emergency Ventilator
- JIUXIN MEDICAL, JIXI H-100 *(5/2/2020)*
  Emergency Ventilator
- Vayu Global Health Innovations, Vayu bubble Continuous Positive Airway Pressure Circuit ('Vayu BCPAP') *(5/5/2020)*
  Continuous Positive Airway Pressure Circuit
- Hunan Beyond Medical Technology Co., Ltd. BEYOND C20A CPAP (5/6/2020)
  Ventilator Continuous Minimal Ventilatory Support
- Hunan Beyond Medical Technology Co., Ltd. BEYOND B30P BiPAP (5/6/2020)
  Ventilator Continuous Minimal Ventilatory Support
- Guangzhou Hypnus Healthcare Co., Ltd. Hypnus ST730. (5/6/2020)
  Ventilator Continuous Minimal Ventilatory Support
- AutoMedX Inc. SAVe II+ (M50016, M50017) (5/7/2020)
  Powered Emergency Resuscitator
- Taiyuan Shanghai Medical, Fabius Plus / Fabius Plus XL (5/8/2020)
  Gas Machine, Anesthesia
- Somnetics International, Inc., Transcend 3 BiPAP (5/8/2020)
  Ventilator, Non-Continuous
- Lanick Med Systems LLC., Lyra x1 and Lyra x2 Ventilators (5/12/2020)
  Ventilator, Non-Continuous, Facility Use
- CMI Health Beijing Aeonmed Shangrila510S (5/15/2020)
  Emergency Transport Ventilator

- SysMed (China) Co., Ltd., VM series-DPAP20 Plus, DPAP25 Plus, DPAP 25 Pro, DPAP 30 Pro (5/18/2020)
  Ventilator, Continuous, Minimal Ventilatory Support

Authorized Ventilator Tubing Connectors
Manufacturer, Product Name, *(Date of Authorization)*

- Prisma Health, Ventilation Expansion Splitter (VESper) *(3/25/2020)*
  VESper allows multiple patients to be treated by a single ventilator
- Vent Multiplexor, LLC., Vent Multiplexor *(4/15/2020)*
  Dual patient circuit connector that is intended to provide temporary rescue mechanical ventilation for dual patient ventilation until an additional ventilator is available
- MakeMedical, VentMI *(4/19/2020)*
  Dual Patient Circuit Connector
- Northwell Health, Inc. Northwell 3D Printed BiPAP Adaptor *(4/29/2020)*
  Ventilator Tubing Connector
- Formlabs Inc., Formlabs 3D Printed BiPAP Adaptor *(4/29/2020)*
  Ventilator Tubing Connector
- Covidien LLC., DAR Adult Dual Patient Breathing Circuit 301P14429 (5/05/2020)
  Dual Patient Circuit Connector
- Safe Flight Instrument Corporation, Safe Flight 9100-3 Quad Vent (5/7/2020)
  Patient Circuit Connector
- Safe Flight Instrument Corporation, Safe Flight 9100-1 Quad Vent (5/7/2020)
  Patient Circuit Connector
- Stryker Instruments, Flow Control Valve (5/8/2020)
  Patient Circuit Connector
- Valhalla Medical Supply, LLC Single-Use Emergency Ventilator 2-Way Manifold (5/13/2020)
  Dual Patient Circuit Connector

Authorized Ventilator Accessories

- SMD Manufacturing, LLC. ReddyPort Mini NIV Access Elbow *(4/13/2020)*
  Mini NIV Access Elbow is intended to provide an interface for application of CPAP or bi-level therapy. The elbow is for single patient use in the hospital/institutional environment

Elbow connector for mask

- 3B Medical, Inc., 3B Hi-Flow H80, Respiratory Humidifier *(4/14/2020)*
  H-80 series humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This device is for patients by prescription in the home or hospital/institutional environment
- Janisys, Janisys CPAP Flow Generator *(4/28/2020)*
  Positive End Expiratory Pressure Breathing Attachment

Infusion Pumps and Infusion Pump Accessories

Manufacturers and other stakeholders	The infusion pumps and infusion pump accessories that are eligible for inclusion under this EUA are those that are not currently cleared or approved in the	Authorizes the use of these products if they meet specific criteria for safety, performance, and labeling. **Authorized products can be found in Appendix A** and listed below:

5/13/2020	U.S. or that are currently cleared in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA.	
Authorized Infusion Pumps: Manufacturer, Product Name, *(Date of Authorization)* **Device** *Description/Intended Use*		
Infusion Pump Accessories Manufacturer, Product Name, *(Date of Authorization)*		

Updated through May 20, 2020