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Note: Be prepared to send the appropriate test reports, certificates, and photographs for each item you submit when you receive a request for information.

Ventilators

Language: English

Mode Capabilities:

- Assist Control Ventilation
- Synchronized Intermittent Mandatory Ventilation
- Pressure Control Ventilation
- Volume Control Ventilation
- Positive End Expiratory Pressure
- Pressure Support
- Blending of Oxygen and Air
- CPAP mode – continuous positive airway pressure

Lead Time: Total order must be available within 4 weeks with at least 25% of the order delivered each week.

Disposable Respirators (N95, N99, N100, R95, P95, P99, P100)

Respirators must:

- Have National Institute for Occupational Safety and Health (NIOSH) Certification (These are formatted TC-84A-xxxx.)
- Contain no natural rubber latex
- Have two head straps to hold the facepiece to the head. Earloops are not acceptable for respirators.

Note: Prior to submittal, verify that the brand of respirator is listed in NIOSH's list of manufacturers or as a private label company:

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html.

In case of severe shortages non-NIOSH-certified respirators can be submitted for consideration. These must have the documentation of non-U.S.A. country respirator certification per Table 1.

Table 1: Acceptable Non-NIOSH Disposable Respirator Classifications in Case of Shortage of NIOSH Certified Respirators

Jurisdiction Performance	Standard	Acceptable Product Classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PPF3, PPF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1 st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

Respirator Made of Elastomeric Material (Half or Full-Face, Non-Disposable)

Respirators must:

- Have NIOSH Certification TC-xxx-xxxx
- Contain no natural rubber latex

Powered Air Purifying Respirator (PAPR)

Respirators must:

- Have NIOSH Certification TC-xxx-xxxx
- Contain no natural rubber latex

Surgical Masks

Surgical masks must:

- Have documentation of U.S. FDA 510(k) clearance.
- Have documentation that establishment and device are registered with the U.S. Food and Drug Administration (FDA) in one of the following product codes:

Classification Regulation	Device Type	Product Code
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel	LYU
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT

- Have test results from an accredited laboratory of testing to ASTM F2100, ASTM F1862 and ASTM F2299; or EN 14683 or YY0469-2011 for filtration efficiency and fluid resistance and identify whether surgical mask meets level 1, 2, 3, or IIR.
- Have minimum dimensions of 17 cm wide by 10 cm high with height expanding to a minimum of 15 cm (measured at the widest point) through use of pleats.
- Be constructed with a minimum of three plies.
- Have adjustable nose bridge constructed with wire or metal band which is completely protected from skin with mask fabric.

Coveralls (Hospitals and EMS)

Coveralls must:

- Be manufactured in an FDA registered facility
- Have product code OEA
- Have documentation of compliance with either:
 - o NFPA 1999 – showing ASTM F1670 and ASTM F1671 testing, or
 - o EN14126 – showing ISO 16603 and ISO 16604 testing and identifying the performance level (1-6).

Isolation and Surgical Gowns

Isolation Gowns

Isolation Gowns must:

- Be manufactured in FDA registered facility.
- Be in FDA product code “OEA”
- Meet ASTM F3352, Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities, www.astm.org.

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- Have documentation of compliance with American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI), ANSI/AAMI PB70 showing what level they meet: 1, 2, 3, or 4.

Surgical Gowns

Surgical Gowns must:

- Be manufactured in an FDA-registered facility
- Be registered with FDA product code “FYA” for surgical gown or “FYC” for surgical isolation gown.
- Meet ASTM F2407 Standard Specification for Surgical Gowns intended for Use in Healthcare Facilities
- Have documentation of compliance with American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI), ANSI/AAMI PB70 showing they meet level 1, 2, 3, or 4.

Face Shields (Disposable and Reusable)

Face Shields must:

- Visors made of acetate, PET, PETG, propionate, or polycarbonate.
- Visors that are at a minimum, full-face length with outer edges of the face shield reaching at least to the point of the ear, and cover the chin and forehead.
- Brow caps or forehead cushions ensuring adequate space to allow for the use of respirator and eyewear.
- Single Velcro, elastic, or ratchet strap.
- Meet Class I or Class II flammability requirement per 16 CFR 1610 or be labeled with a recommendation against use in the presence of high intensity heat source or flammable gas.

Preferred Face Shields include:

- FDA registered
- Treated for anti-glare, anti-fog, and/or anti-static

Goggles

Goggles must:

- Indirectly vented.
- Have manufacturer’s anti-fog coating.

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Preferred Goggles include:

- Marking “D3” for splash or droplet protection.

Examination Gloves

Examination Gloves must:

- Be medical grade
- Be manufactured by an FDA registered facility and have FDA 510(K) clearance.
- Have one of the following FDA product codes:
- Vinyl – “LYZ”
- Nitrile – “LZA”
- Be labeled: “not made with natural rubber latex”.
- Be powder-free
- Be available in sizes: S-XL
- Have a minimum length of 220mm-230mm depending on glove size and material type.
- Have documentation showing they meet the appropriate American Society for Testing and Materials (ASTM) standard for patient examination gloves:
 - o ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
 - o ASTM D5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application

Hand Sanitizer

Hand Sanitizer must:

- Contain 60% ethanol or 70% isopropanol
- Be FDA registered

Surface Wipes

Surface Wipes must:

- Appear on the Environmental Protection Agency’s List N:
<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-CoV-2>
- Be registered by the California Department of Pesticide Regulation for sale in California: <https://apps.cdpr.ca.gov/docs/label/labelque.cfm>

Swabs

Swabs must be FDA approved:

- Puritan Nasopharyngeal swabs: 25-3317-H, 25-1406 1PF 50f, 25-800 1PD 50**, 25-3320-U, 25-3320-H EMB 80, 25-3320-U EMB 80, 25-3320-H EMB 100 and 25-3320-U EMB 100
- Copan Nasopharyngeal swabs: 503CS01, 518CS01, and 501CS01, 502CS01
- BD Nasopharyngeal swabs: 220252 and 220251
- DHI/Quidel Nasopharyngeal swabs: 503CS01.DHI
- Fisher Healthcare Nasopharyngeal swabs: 23600952, 23600956 and 23600950 Puritan Oropharyngeal swabs: 25-1506 1PF SOLIDf, 25-1506 1PF 100f, 25-3206-H, 25-3206-U, 25-3706-H, 25-806 1PD** and 25-806 1PD BT**
- Copan Oropharyngeal swabs: 502CS01, 519CS01, 164KS01**, 167KS01**, 170KS01** and 175KS01**
- BD Oropharyngeal swabs: 220250
- Fisher Healthcare Oropharyngeal swabs: 23600950, 23600957, 1490641**, 1490640** and 1490650**
- Additional sterile flocked swabs from Puritan that may be used: 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 25-3320-U, 25-3320-H and 25-3319-H

Viral Testing Media

Viral Transport Media (VTM) / Universal Transport Media Kits (Complete Sample Collection Kits with both swab & media):

- FYI: nasopharyngeal (NP) preferred, other types acceptable; should be shelf-stable (i.e., no refrigeration requirements); volume of media could be in the 1-3 mL range depending on product.
- Examples of product SKUs:
 - o BD Brand: 220222, 220526, 220527, 220529, 220531 (all are described as UVT kits)
 - o Puritan: UT-367; UT-316; UT-317
 - o VTM / Universal Transport only
- Examples of product SKUs:
 - o BD Brand: 220220
 - o Puritan: UT-300;
 - o Remel: R12506, R12505