COVID-19 Essentials: Masks

Frequently Asked Questions

Q: What are your inventory levels and how are you managing ongoing?

A: Since the beginning of the COVID-19 crisis, we have been in close contact with Senior Living providers and other customers to understand their current volume and future needs for masks. We have more than enough inventory on hand to meet the immediate need for product availability and will be receiving ongoing inventory from our factories to ensure that we do not run out of stock.

If you or your organization are interested in increasing access to Food & Drug Administration (FDA)-listed masks ongoing, please contact your dedicated account manager or corporate account manager, or call 800-634-7328 to discuss further.

Q: What regulatory guidance exists from the CDC and OSHA regarding mask specifications for use during the COVID-19 pandemic?

A: The chart below is an excerpt of the chart provided by the Centers for Disease Control (CDC), offering guidance for product usage as part of a crisis capacity strategy:

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
People's Republic of China	GB 2626-2006 or GB 2626-2019	KN/KP95	N95
People's Republic of China	GB19083-2010	KN/KP100	N95
Europe	EN 149-2001	P2	N95
Europe	EN 149-2001	P3	N99 or lower

OSHA has provided similar guidance:
https://www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under

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		KN/KP100	N99 or lower
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Q: Are these masks Food & Drug Administration (FDA) approved?

A: There are two ways in which the FDA permits masks to be sold as medical devices in the United States during a public health emergency.

First, a manufacturer may follow the standard FDA registration and listing process, which requires an FDA operator number and product code. Alternatively, a manufacturer may meet the requirements of an Emergency Use Authorization (EUA).

Provided below are the certifications and FDA product codes or EUA our masks adhere to:

Direct Supply Item #	Product Description	Standard/Certification	FDA Operator Number	FDA Product Code
8VB21	3 Ply Disposable Face Masks with Earloops	EN149:2001+A1:2009 (FFP1) GB/T 32610-2016	10063132	LYU
8XB56	KN95 Disposable Masks, Small	EN149:2001+A1:2009 (FFP2) GB 2626:2006	10067858	LYU
8VK51	KN95 Disposable Masks	EN149:2001+A1:2009 (FFP2) GB 2626:2006	10067858	LYU
8X849	N95 Disposable Masks, NIOSH Approved	NIOSH TC Number: 84A-7638	NA: See EUA details below	NA: See EUA details below

Q: Are the N95 masks part of the FDA's EUA authorization?

A: The FDA issued a blanket EUA for disposable filtering facepiece respirators approved by the National Institute for Occupational Safety and Health (NIOSH). The EUA permits NIOSH-approved N95s to be used in a healthcare setting during the public health emergency.

Q: Why does the box for some masks say "Not a medical device or non-medical product"?

A: Due to recent changes from Customs, we are now required to include additional labeling on the packaging.

Our masks, which are FDA listed and produced by FDA-registered manufacturing facilities, **are intended for use in general healthcare settings, but are not intended for surgical settings.** Also, these masks should not be used during aerosol-generating medical procedures unless the alternative is a loose-fitting surgical mask or improvised device.

Q: Are the KN95 masks NIOSH or CDC certified?

A: No. NIOSH is part of the CDC, so it's a U.S. agency. If NIOSH tested the product, it would be rated N95, N99, etc. The CDC does not certify products.

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Q: What is your testing criteria?

A: For the 3 Ply Mask, the masks meet China standard GB/T32610 and EN149:2001+A1:2009 (FFP1). Products are randomly sampled by an independent third-party lab to the testing criteria listed below to help ensure quality and performance:

Particulate Filtration Efficiency (PFE) >=90% (@0.3μm)
Earloop Pull Force >=20 Newtons
Breathability (Inspiratory Resistance<=175Pa, Expiratory Resistance<=145Pa

On the KN95 and N95 Masks, the masks are randomly sampled by an independent third-party lab to the testing criteria listed below to help ensure quality and performance:

Particulate Filtration Efficiency (PFE) >=95% (@0.3μm, air flow at 85L/min)
Earloop Pull Force >=10 Newtons
Breathability (Inspiratory Resistance <=350Pa, Expiratory Resistance<=250Pa)

Q: Are there any limits to how many masks I can buy?

A: So that we can ensure that we have enough inventory on hand, there are currently weekly limits in place:

#8XB56 Masks – temporarily limited to 16 or fewer boxes per week, per facility

If your corporation is interested in removing order maximum limitations, please contact your dedicated corporate account manager to discuss further.