COVID-19 Essentials: Masks

Frequently Asked Questions

Q: What are your inventory levels and how are you managing on-going?

A: Since the beginning of the COVID 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 on-going inventory from our factories to ensure that we do not run out of stock.

If you or your organization is interested in increasing access to FDA listed masks ongoing, please contact your dedicated account manager, corporate account manager or call 800-634-7328 to discuss further.

Q: What regulatory guidance exists regarding masks specifications for use during the COVID-19 pandemic?

A: The chart below is an excerpt of the chart provided by the Center 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

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	KN/KP95	N95
		KN/KP100	N99 or lower
Europe	EN 149-2001	P2	N95
		P3	N99 or lower

Q: Are these masks Food & Drug Administration (FDA) approved?

A: The standard FDA registration and listing process is the 'gold standard' that applies even during non-emergency times – **all masks sold by Direct Supply meet this standard.**

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Provided below are the certifications and FDA product codes our masks meet:

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

Q: Are the KN95 masks part of the FDA's EUA authorization?

A: The FDA issued an 'Emergency Use Authorization' process for Non-NIOSH Approved Respirators manufactured in China. The EUA allows respirators which were not previously sold in the U.S., but tested/certified by certain third parties, to be sold for the duration of the public health emergency.

Masks sold by Direct Supply are currently not on this list. They are FDA listed and may be sold under existing FDA regulations.

Many other KN95s are **no longer** authorized. The FDA has said its change in guidance was due to minimum particulate filtration efficiency testing conducted at NIOSH on some respirators that were originally authorized on Appendix A.

See "What is your testing criteria?" for more details about how masks sold by Direct Supply are tested by independent third parties to help ensure quality and performance.

Q: Why does the box 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 are FDA-listed and produced by FDA-registered manufacturing facilities. **They are intended for use in general healthcare settings, but are not intended for surgical settings.**

These masks should also 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 the American National Institute for Occupational Safety, which is part of the CDC, so it's a US agency. If NIOSH tested the product, it would be rated N95, N99, etc. The Center for Disease Control (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 Mask, the masks meet China standard GB2626:2006 and EN149:2001+A1:2009 (FFP2). 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) >=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:

3-Ply Masks - Temporarily limited to 34 or fewer boxes per week, per facility.
KN95 Masks - Temporarily limited to 8 or fewer boxes per week, per facility.

If your Corporation is interested in removing order maximum limitations of FDA-listed masks, please contact your dedicated Corporate Account Manager to discuss further.