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 regarding mask and/or respirator specifications for use during the COVID-19 pandemic?

A: Several different agencies have issued regulatory guidance impacting the selection and use of masks and respirators during the COVID-19 pandemic. This includes but is not limited to the Food & Drug Administration (FDA), the Centers for Disease Control & Prevention (CDC), Occupational Safety & Health Administration (OSHA), and State/local licensing agencies. Over the past few months, the regulatory guidance has continued to change rapidly and in general most agencies now expect that facilities have returned to conventional use practices.

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

A: There are multiple 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). Note that as of July 2021 the FDA has begun revoking many of its previously issued EUAs, and it is anticipated that this trend will continue. Finally, the FDA may follow enforcement discretion to permit certain products to be sold within the U.S. market during the public health emergency.

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
GG367	3 Ply Disposable Face Masks with Earloops	EN14683:2019+AC:2019 Type IIR	10063323	LYU
8VB21	3 Ply Disposable Face Masks with Earloops	EN149:2001+A1:2009 (FFP1) GB/T 32610-2016	10063132	LYU

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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
GMF90	KN95 Disposable Masks, FDA	EN149:2001+A1:2009 (FFP2) GB2626:2019	10062832	LYU
8X849	N95 Disposable Masks, NIOSH Approved	NIOSH TC Number: 84A-7638	NA: See EUA details below	NA: See EUA details below
FQ942	N95 Disposable Masks, NIOSH Approved, Small	NIOSH TC Number: 84A-5463	8043227	MSH
8VDQ1	N95 Disposable Mask, NIOSH Approved, 20/box	NIOSH TC Number: 84A-5411	8043227	MSH
GT389	3M 9010 N95 Folded Disposable Respirator, NIOSH Approved	NIOSH TC Number 84A-4243	NA: See EUA details below	NA: See EUA details below
GT390	3M 9502+ N95 Folded Disposable Respirator, NIOSH Approved	NIOSH TC Number 84A-8637	NA: See EUA details below	NA: See EUA details below

Q: Are the N95 masks part of an FDA 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 by Healthcare Personnel pursuant to CDC's recommendations to prevent Healthcare Personnel exposure to pathogenic biological airborne particulates during the public health emergency. As of July 2, 2021 this EUA remains in place.

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

A: As of July 6th, 2021, the FDA is revoking EUAs for for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China; these devices will no longer be authorized for use as respirators by health care personnel in health care settings. Customers should follow the latest guidance and check with their local Authority Having Jurisdiction (for example OSHA surveyor, CMS surveyor, State licensing agency, etc.) to

verify whether KN95s may be used for other purposes, such as source control, in a particular facility.

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.

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)