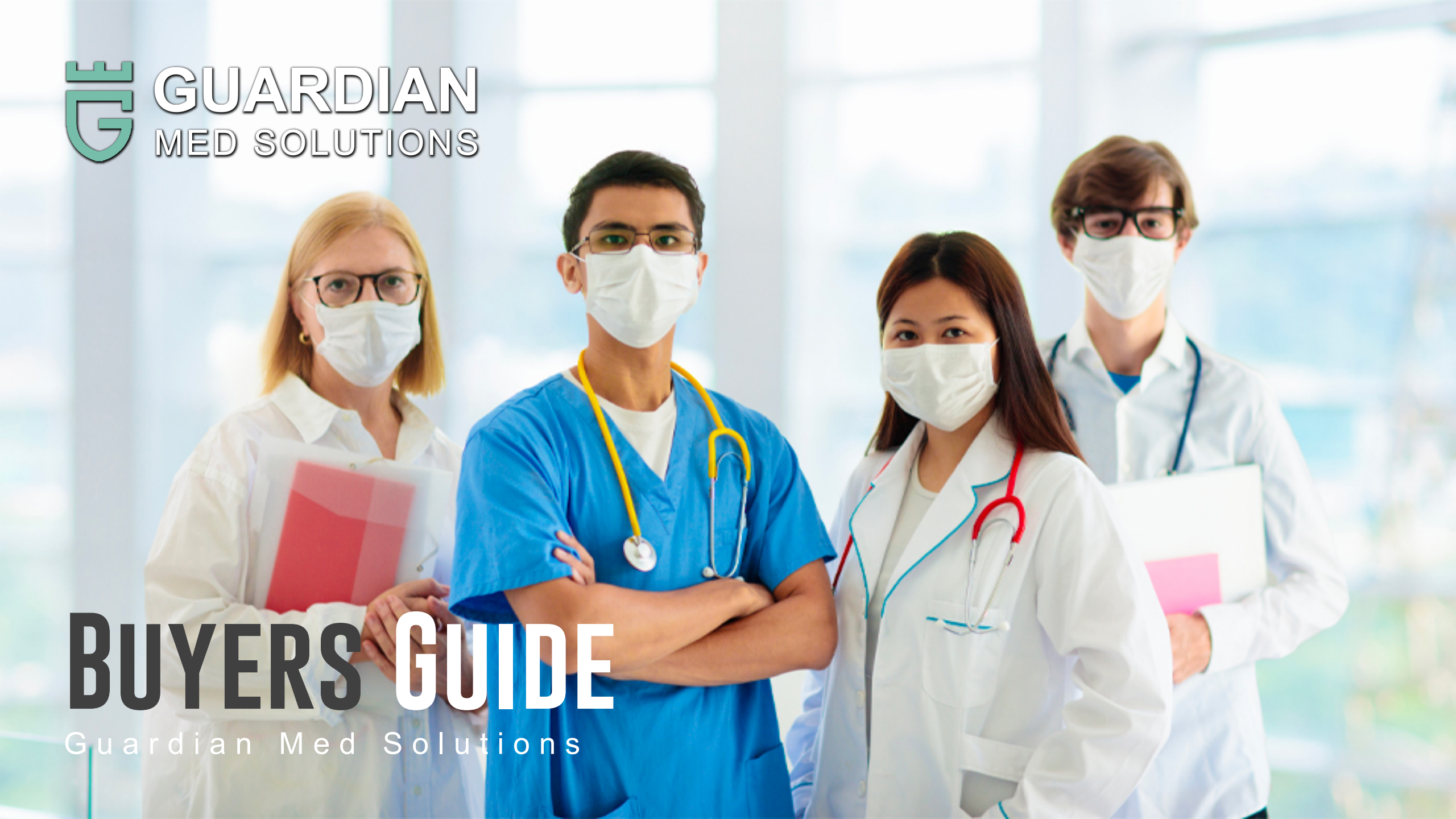
GUARDIAN
MED SOLUTIONS



BUYERS GUIDE

Guardian Med Solutions

TABLE OF CONTENTS

1 *Logistics*

2 *Shipping & Delivery*

3 *Financials & Documentation*

4 *Mask Selection Guide*

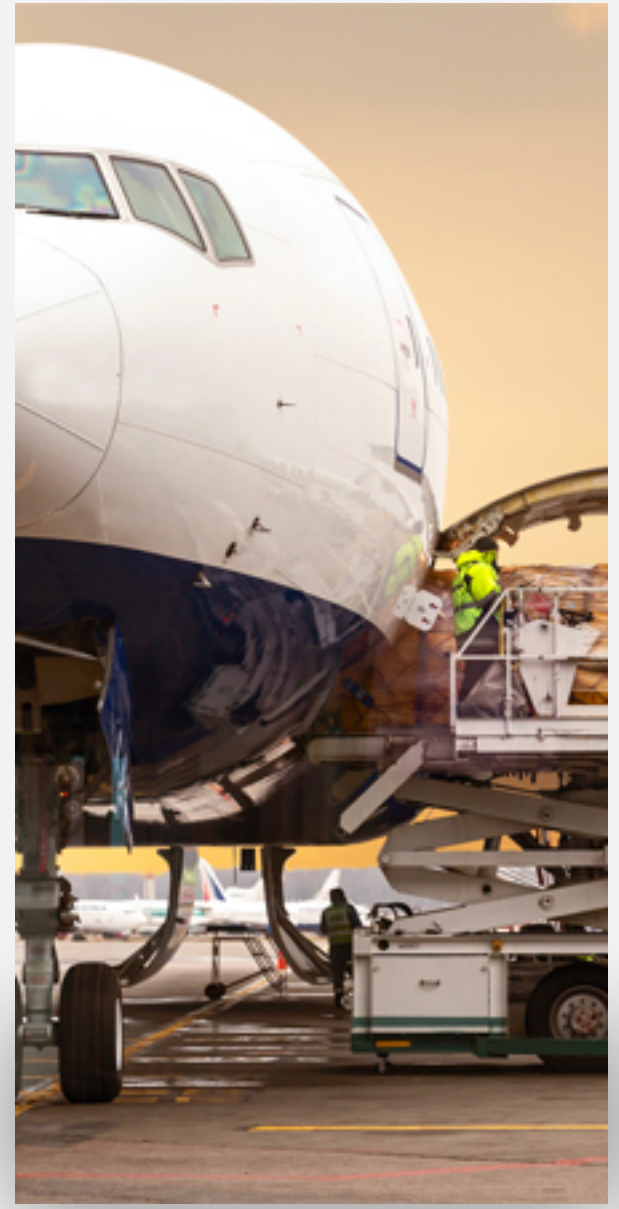
5 *Personal Protective Equipment (PPE)*

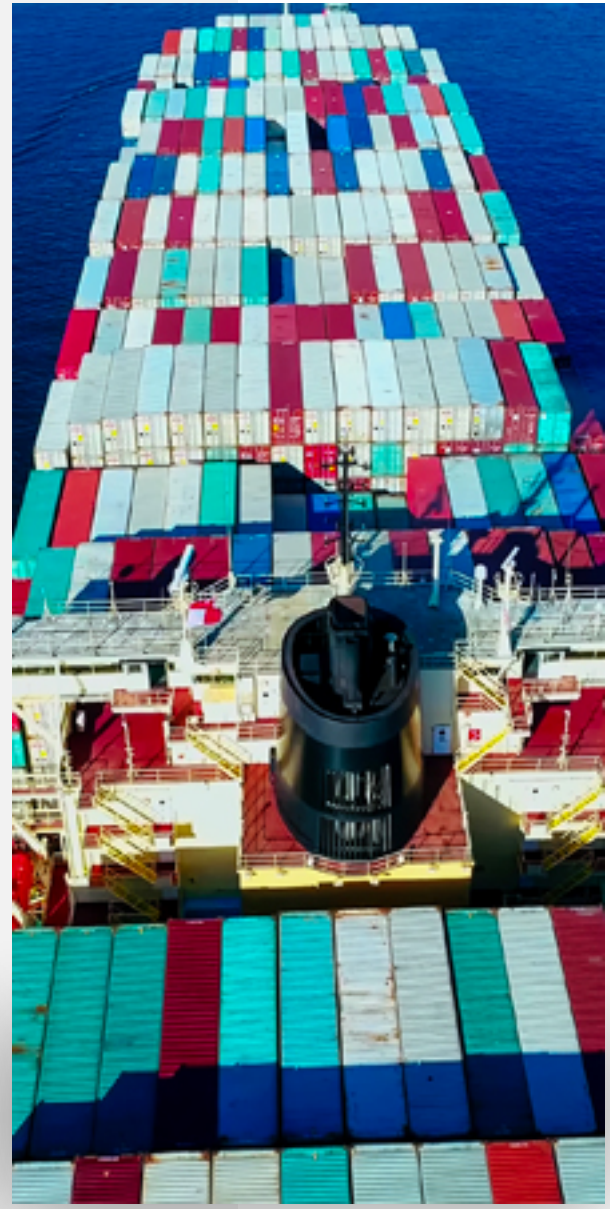
6 *Factory Photos*

7 *Latest news*

LOGISTICS

1. Partnered with Exact Direct Logistics Company
2. 10+ Years Specializing in International Shipping
3. FDA Licensed Importer
4. Large quantities kept in stock at our warehouses
   - 100k sq ft Warehouse in Marietta, GA
   - 105k sq ft Warehouse in Rancho Cucamonga, CA
5. Customs Brokerage
   - Experience in getting Chinese & American Customs cleared in a timely fashion
   - Currently Clearing Customs prior to hitting the ground in the U.S.
   - Remaining diligent on the evolving Customs & Regulatory Changes
6. Partnered with a Chinese National
   - Located in China Now
   - Licensed Medical Exporter
   - Working In-person with Factory Partners
   - Seeing off daily shipments
7. Factories
   - Sourcing from 14 Total Factories
   - Relationships with 4 Factories for 2+ Years prior to Covid





SHIPPING & DELIVERY

Shipping Methods

- Air Freight
- Private Air
- Ocean Cargo
- Military Cargo

Overseas Delivery Times

- Air: 8-12 Days
- Ocean Cargo to West Coast: 2 Weeks
- Ocean Cargo to East Coast: 4 Weeks

Domestic Delivery Times

- Within 24 hours

Financials & Documentation

Financials

Product in the U.S.
Or
Government & Healthcare

- 0% Down
- 100% When Delivered

Placing Orders Overseas
Or
Individuals / Brokers

- 50% Down
- 50% When Delivered

Documentation Provided with Purchase

- Purchase Agreement with our U.S. Entity
- Proof of Life Videos
- Factory Pictures
- Product Pictures
- Video Conference with Factory or our Partner at the Factory

GUIDE TO FACE MASK SELECTION AND USE

ASTM PERFORMANCE LEVELS ▲ ▼

MAXIMUM FILTRATION

NIOSH Approved N95 / KN95 Particulate Respirator

High Fluid Resistance	160 mmHg
Filtration Efficiency	PFE = 99.9% @ 0.1 micron
Breathability - Delta P	> 5.0 mm H_2O/cm^2
Flame Spread	Class 1

N95
KN95

Indicated for use when treating patients with airborne diseases such as TB or influenza.*

Meets CE 0121 – In reference to EN 149: 2001 FFP2 NR.

Pictured: Isolator Plus™ N95 Particulate Respirator

ASTM LEVEL 3

High Fluid Resistance	160 mmHg
Filtration Efficiency	BFE ≥ 98% PFE ≥ 98% @ 0.1 micron
Breathability - Delta P	< 5.0 mm H_2O/cm^2
Flame Spread	Class 1

LEVEL 3

Ideal for procedures where heavy to moderate amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type IIR Standard.

Pictured: Ultra® Sensitive Earloop with Secure Fit® Mask Technology

ASTM LEVEL 2

Moderate Fluid Resistance	120 mmHg
Filtration Efficiency	BFE ≥ 98% PFE ≥ 98% @ 0.1 micron
Breathability - Delta P	< 5.0 mm H_2O/cm^2
Flame Spread	Class 1

LEVEL 2

Ideal for procedures where moderate to light amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type IIR Standard.

Pictured: Procedural Earloop with Secure Fit® Mask Technology

ASTM LEVEL 1

Low Fluid Resistance	80 mmHg
Filtration Efficiency	BFE ≥ 95% PFE ≥ 95% @ 0.1 micron
Breathability - Delta P	< 4.0 mm H_2O/cm^2
Flame Spread	Class 1

LEVEL 1

Ideal for procedures where low amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type II Standard.

Pictured: Isofluid® Earloop with Secure Fit® Mask Technology

LOW PERFORMANCE

Surgical Molded Utility Mask
Physical Barrier Only
No LEVEL Performance Level **
Filtration Efficiency N/A

**Unless mask manufacturer certifies mask meets ASTM performance Level 1

Ideal as a comfortable substitute for earloop face masks, this mask is a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.

Pictured: Surgical Molded

MINIMUM PERFORMANCE

Utility Mask (Tissue/Tissue)
Physical Barrier Only
No LEVEL Performance Level
Filtration Efficiency N/A

Ideal as a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.

Pictured: Isolite® Earloop

Understanding ASTM Face Mask Performance Levels

FEATURE	EXPLANATION
Fluid Resistance	Mask resistance to penetration by synthetic blood under pressure (mmHg). Higher fluid resistance = Higher protection.
BFE - Bacterial Filtration Efficiency	Percentage of aerosol particles filtered at a size of 3 microns.
PFE - Submicron Particle Filtration Efficiency	Percentage of submicron particles filtered at 0.1 microns.
Delta P - Differential Pressure	Pressure drop across mask, or resistance to air flow in mmH_2O/cm^2. Greater resistance = better filtration but less breathability.
Flame Spread	Measures the flame spread of the mask material.

FULL LENGTH FACE SHIELD

- Optically clear, distortion-free wrap-around face shield.
- 1 ½" foam headband holds shield away from face; "floats" lightly on forehead, with no pressure on temples; vented for increased air flow.
- Protects mask and face from direct splatter; may prolong mask life.
- Sonically welded elastic headband for added strength.
- Anti-fog treatment on inside and outside of shield.
- Available in 7" and 9" options

PERSONAL PROTECTIVE EQUIPMENT (PPE)

3D Disposable Mask

FACTORY: NAFY

NMPA: N/A (NON-MEDICAL)

FDA#: REGISTRATION NO#30000263041

SKU#: M014 FACTORY SKU#EPLY

PRODUCT MEASUREMENTS:
31 X 21 cm

UNIT WEIGHT:
5.1 gm

OUTER CARTON:

FABRIC COMPONENTS **3 LAYERS**

nonwoven
meltblown
nonwoven

REPORT AVAILABILITY:
- CE Certificate
- Chinese GB Test Report
- FDA

PRODUCTION NOTES:
500,000 Daily

PERSONAL PROTECTIVE EQUIPMENT (PPE)

KN95/FPP2 Protective Mask

FACTORY: GYJK

NMPA: N/A (NON-MEDICAL)

FDA#:

SKU#: M016/ FACTORY SKU#JK-N001

FABRIC COMPONENTS **5 LAYERS**

nonwoven

meltblown

meltblown

Hot wind cotton

nonwoven

PRODUCT MEASUREMENTS:
16 X 11 cm

UNIT WEIGHT:
8.6 gm

REPORT AVAILABILITY:

- CE Certificate
- Chinese GB Test Report

PRODUCTION NOTES:
500,000 Daily

OUTER CARTON:

PERSONAL PROTECTIVE EQUIPMENT (PPE)

KN95 Dr. Huayue Protective Mask

FACTORY: JIANGMEN HUAYUE

NMPA: N/A (NON-MEDICAL)

FDA#:
Owner/Operator Number: 10064633
Listing No#D379565
Establishment No#3016699678

SKU#: M036

FABRIC COMPONENTS **5 LAYERS**

PRODUCT MEASUREMENTS:
31 X 21 cm

UNIT WEIGHT:
5.1 gm

REPORT AVAILABILITY:
- CE Certificate
- Chinese GB Test Report
- FDA

PRODUCTION NOTES:
500,000 Daily

OUTER CARTON:

PERSONAL PROTECTIVE EQUIPMENT (PPE)

KN95 Protective Mask

FACTORY: Tianjin Benmo

NMPA: N/A (non-medical)

FDA#: EUA White List

SKU#: M038

FABRIC COMPONENTS **5 LAYERS**

nonwoven

meltblown

meltblown

Hot wind cotton

nonwoven

PRODUCT MEASUREMENTS:
15.5 x 21 cm

UNIT WEIGHT:
11 gm

REPORT AVAILABILITY:

- CE Certificate
- Chinese GB Test Report
- FDA

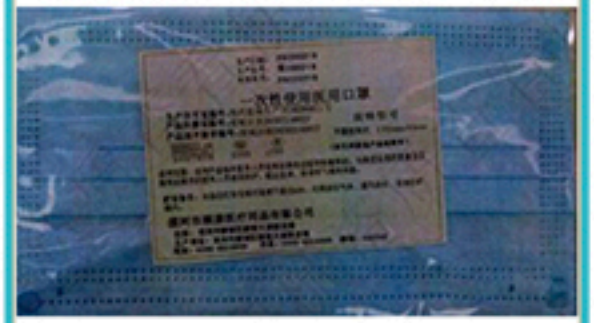
PRODUCTION NOTES:
100,000 Daily

OUTER CARTON:


CE Certificate of Conformity

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Disposable Medical Mask



FACTORY: LHSK

NMPA: N/A

FDA#:
Owner/Operator Number: 10062906
Listing No#D374773 (MSH)
Listing No#D374774 (KHA)
Registration No#3016699601

SKU#: M024

FABRIC COMPONENTS **3 LAYERS**

nonwoven

meltblown

nonwoven

PRODUCT MEASUREMENTS:
17.5 x 9.5 cm

UNIT WEIGHT:
3.4 gm

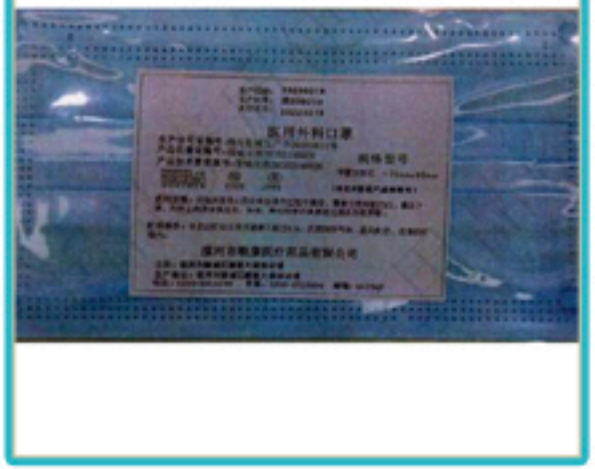
REPORT AVAILABILITY:
- CE Certificate
- Chinese GB Test Report
- FDA

PRODUCTION NOTES:
500,000 Daily

OUTER CARTON:

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Surgical Mask



FACTORY: LHSK

NMPA: N/A

FDA#:
Owner/Operator Number: 10062906
Listing No#D374773 (MSH)
Listing No#D374774 (KHA)
Registration No#3016699601

SKU#: MS24

FABRIC COMPONENTS **3 LAYERS**

nonwoven

meltblown

nonwoven

PRODUCT MEASUREMENTS:
17.5 x 9.5 cm

UNIT WEIGHT:
3.3 gm

REPORT AVAILABILITY:
- CE Certificate
- Chinese GB Test Report
- FDA

PRODUCTION NOTES:
500,000 Daily

OUTER CARTON:

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Hand Sanitizers

FACTORY: Zhongkebaishi Health Industry

NMPA: N/A (non-medical)

FDA#: 7813-2001-1

SKU#: C071

PRODUCT MEASUREMENTS:
17.5 x14 cm

UNIT WEIGHT:
28 gm

TOTAL ANCILLARY

REPORT AVAILABILITY:
- CE Certificate
- Test Report
- Safety Data Sheet

PRODUCTION NOTES:
300,000 Weekly


Fiscal Year 2020 USA FDA
CERTIFICATION OF REGISTRATION

Factory Photos

FACTORY PHOTOS

Assembly / Production

Assembly / Production

Assembly / Production

Assembly / Production

Assembly / Production

Assembly / Production

Inspection

Inspection

Quality Control

LATEST NEWS

FDA changes course and allows China's KN95 mask to be used in US

By Geneva Sands and Cristina Alesci, CNN
Updated 4:17 PM ET, Fri April 3, 2020

CNN politics • LIVE TV

(CNN) — The US Food and Drug Administration on Friday changed its position on a sought-after type of respirator from China, the KN95, announcing that the agency will authorize the mask for use in healthcare settings if it meets certain criteria.

In response to continued respirator shortages, the FDA issued new guidance, authorizing KN95 respirators if certain criteria are met, including evidence demonstrating that the respirator is authentic.

The move comes after conflicting government guidance that caused confusion over how these masks should be used and whether they could be imported into the US.

LISTEN: The Coronavirus: Fact vs. Fiction Podcast

The FDA did not include these masks on its initial guidance for emergency use issued last month, but the Centers for Disease Control and Prevention said the KN95 masks are "expected to be suitable alternatives" to the N95

FDA changes course and allows China's KN95 mask to be used in US - CNNPolitics 4/7/20, 12:23 PM

masks during the coronavirus pandemic when supplies are short.

The differing guidance left suppliers hesitant to ship masks and US buyers wary of purchasing them.

On March 28, the FDA listed masks from six countries, including Mexico and Brazil, that it found "appropriate to protect public health or safety," but left the Chinese masks off the list.

Across the globe, N95 masks -- considered the gold standard of respirator masks -- are in short supply. These masks, which filter out at least 95% of very small particles from the air, are a crucial piece of equipment for doctors and nurses treating the tens of thousands of coronavirus-infected patients in the United States.

But questions about the quality and effectiveness of the similarly named KN95 mask arose as production ramped up in China.

The masks were not listed in the initial FDA emergency use authorization because of "challenges in determining the authenticity" of the imports, said an agency spokesperson, who added that the FDA has already encountered fraudulent products identified as KN95s.

In one instance, a business executive who was worried about hospitals refusing to use the KN95 decided against putting KN95 masks on a plane bound for the US because the FDA hadn't issued a blanket "emergency use authorization" for hospitals to use Chinese KN95 masks.

"(Y)ou have a country (China) that's proven it has masks effective in a hospital setting," said the executive. "Why not let Chinese KN95 masks in?"

At least two Change.org petitions were started asking the FDA to change its protocol and allow the use of KN95 masks.

Hospitals would not accept the Chinese KN95 masks without FDA approval, according to John Wood, a former Microsoft China executive who founded the education nonprofit "Room to Read."

Wood and his wife Amy Powell, who are based in Hong Kong, recently started a private effort accepting financial donations, which are used to source multiple types of masks -- including KN95 -- in China in an effort to deliver them to US health care workers in need.

"We have huge demand. And we have donors who are willing to underwrite it and you've got the FDA freezing the market," Wood told CNN. They have requests for more than 5 million masks, including from hospitals such as Weill Cornell, Brigham and Women's Hospital and University of Wisconsin Madison.

KN95s helped China in its fight against the coronavirus, according to Wood, who said the US government has failed to make sure there is an adequate supply of N95 masks. Demand froze, because hospitals were afraid to import them and supply was frozen because producers were afraid of getting them confiscated, he said.

Their first shipments arrived in the US on Thursday destined for various places where health care workers or their families had reached out for help, including Seattle, San Francisco, Toronto and Tokyo.

https://www.cnn.com/2020/04/03/politics/fda-china-kn95-us-certain-criteria/index.html

THE HILL

FDA to allow imports of KN95 m from China amid PPE shortage

BY J. EDWARD MORENO - 04/02/20 10:59 PM EDT

1,905 SHARES SHARE TWEET

The Food and Drug Administration (FDA) will no longer block the import of KN95 masks, due to a shortage in personal protective equipment, or PPE, in the United States, an agency official first told Buzzfeed News.

The masks have been described as the Chinese equivalent of an N95 mask which U.S. health care workers use to protect themselves from airborne bacteria and viruses. Though they are allowing imports of the KN95 mask, the product is not FDA-approved, meaning those who use it do so without legal protections.

The Centers for Disease Control and Prevention (CDC) has included the KN95 mask as an alternative to other certified masks that should be used on an emergency basis.

The FDA has not authorized models of KN95 masks made in China under an Emergency Use Authorization (EUA) previously due to concerns of fraudulent products.

"Because of this, the FDA generally would not object to the importation and use of KN95 masks without an EUA," an FDA official told The Hill. "Although not required, if a KN95 mask does not have an EUA, importers may want to take appropriate steps to verify the authenticity of these products. The FDA is ready and available to engage with importers to minimize disruptions during the importing process."

The agency announced Thursday that it was loosening regulations on face masks but did not specifically name the KN95 mask.

Just In...

Graham backs Trump, vows no money for WHO in next funding bill
SENATE — 27M 7S AGO

Mattis defends Pentagon IG removed by Trump
ADMINISTRATION — 38M 55S AGO

Trump shakes up WH communications team
ADMINISTRATION — 56M 39S AGO

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SENATE — 1H 13M AGO

Drugmaker caps insulin costs at $35 to help diabetes patients during pandemic
HEALTHCARE — 1H 20M AGO

Phase-four virus relief hits a wall
SENATE — 1H 28M AGO

President tightens grip on federal watchdogs
ADMINISTRATION — 1H 30M AGO

VIEW ALL

LATEST NEWS

FDA Article on KN95 Masks

FDA Article on K95 Masks 04/05/2020

Q2. Can respirators approved under standards used in other countries, such as KN95, be used in the US during the COVID-19 pandemic?

Yes. The FDA is working diligently to mitigate any potential shortages in the supply chain and taking action to assure health care personnel on the front lines have sufficient supplies of respiratory protective devices. The FDA concluded, based on the totality of scientific evidence available, that certain imported respirators that are not NIOSH-approved are appropriate to protect the public health or safety.

On March 24, 2020, the FDA issued an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators. Under this EUA, among other criteria, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea and Mexico who have similar standards to NIOSH. The FDA did not list KN95 respirators made per China's standards in this EUA because of concerns about fraudulent products listed as KN95s. On April 3, 2020, in response to continued respirator shortages, the FDA issued a new EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

The FDA also issued guidance to provide a policy to help expand the availability of general use face masks for the general public and respirators for health care professionals during this pandemic. The guidance applies to KN95 respirators as well. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN95 respirators, if they are on the Centers for Disease Control and Prevention (CDC) list of respirator alternatives during the COVID-19 pandemic. Although not required, if a KN95 respirator does not have an EUA, importers may want to take appropriate steps to verify authenticity of these products.

The FDA is ready and available to engage with importers to minimize disruptions during the importing process. The FDA established a special email inbox, COVID19FDAIMPORTINQUIRIES@fda.hhs.gov, for industry representatives to quickly communicate with the agency and address questions or concerns.

FDA U.S. FOOD & DRUG ADMINISTRATION

April 3, 2020

To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators;
Health Care Personnel;
Hospital Purchasing Departments and Distributors;
Importers and Commercial Wholesalers; and
Any Other Applicable Stakeholders.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the Coronavirus Disease 2019 (COVID-19) outbreak, subject to the terms of any authorization issued under that Section.[1]

On April 3, 2020, in response to this evolving public health emergency and continued concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available that certain product classifications for imported disposable FFRs that are manufactured in China and not NIOSH-approved and for which data exists that supports the respirators' authenticity, are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized respirators listed in Appendix A are authorized for use in healthcare settings by healthcare personnel (HCP)[2] when used in accordance with CDC recommendations to prevent wearer

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 4, 2020). U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. March 2, 2020.

[2] Healthcare personnel refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel.

exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

This EUA does not affect the previous March 28, 2020, EUA for Non-NIOSH-Approved Imported FFRs (originally issued on March 24, 2020), which authorizes, in part, the emergency use of certain imported disposable FFRs that are not NIOSH-approved and excluded those manufactured in China, to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, pursuant to Section 564 of the Act. FDA is issuing this EUA to authorize disposable respirators manufactured in China that meet certain criteria, including additional validation and review by FDA to confirm the respirator's authenticity.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the authorized respirators, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 pandemic.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators. This EUA does not permit use of authorized respirators by the general public.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized respirators as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence and other information available to FDA, it is reasonable to believe that the authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID-19, outweigh the known and potential risks of such products; and

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