State of West Virginia
**OFFICE OF THE SECRETARY**
**DEPARTMENT OF MILITARY AFFAIRS AND PUBLIC SAFETY**
Building 1, Suite W-400
1900 Kanawha Blvd., East
Charleston, West Virginia 25305
Telephone: (304) 558-2930
Facsimile: (304) 558-6221

**JEFF S. SANDY CFE, CAMS**
**CABINET SECRETARY**

**THOMAS L. KIRK**
**DEPUTY SECRETARY**

**Date:** Thursday, April 16, 2020

**To:** West Virginia First Responders

**From:** Jeff S. Sandy, Cabinet Secretary, CFE, CAMS

**Re:** Allegation of Counterfeit N95 Masks

As I stated in the teleconference on April 16, 2020, I am proud of what you do and are achieving every day for all of us.

I wish to explain the review of the respirator masks recently provided to first responders. In summary:

- These masks are genuine products from Shanghai Dasheng Health Products Manufacture Co. Ltd (Dasheng), and not counterfeits.
- The state purchased 100,000 Dasheng brand N 95 masks; models DTC3X and DTC3B. DTC3B contains a head band and DTC3X contains ear loops.
- The DTC3X model is a KN95 model which is the Chinese model. (Note 1)
- NIOSH has performed OSHA's Quantitative Fit Test on a respirator (brand name unknown) with ear loops and states with a poor fit, it would not provide an acceptable efficiency level of 95%.
- For respirators with ear loops, the CDC stresses the importance of a proper fit while wearing them to ensure they provide the designed level of protection.
- The FDA has concluded that this type of respirator is appropriate to protect public health or safety

**Note 1**

On March 2, 2020, both the CDC and FDA approved the import of KN95 masks into the United States. The CDC stated that the KN95 masks were one of numerous "suitable alternatives" to N95 masks "when supplies are short.".


In addition, on April 16, 2020, Secretary Sandy contacted the Israeli Intelligence Service and inquired about their nations use of masks. They advised that they had purchased millions of dollars' worth of KN95 masks with ear loops. To the left is a picture of the mayor of Jerusalem on April 2 with an KN95 ear loop mask.

**Background**

On Friday, April 10, a West Virginia fire department chief advised DHSEM that he had watched a video conference with the W.Va. Professional Fire Chiefs Association and advised "the state had distributed several counterfeit N95s to the various county 911 directors."

The website referenced was as follows:

***https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html***

DMAPS reviewed the CDC website, which listed several counterfeit masks. These counterfeits include masks made to appear as if they had been manufactured by Dasheng. The fire chief was concerned because that's the company name on the DTC3X N95 masks purchased for first responders from a West Virginia vendor.

More than 50,000 of these masks were distributed, as follows:

- 40,000 to city and county law enforcement, all firefighters, and county emergency management agencies
- 9,000 to the W.Va. Division of Corrections and Rehabilitation
- 1,600 to two hospitals

The contract with the vendor was for Shanghai Dasheng Health Products Manufacture Co. Ltd (Dasheng) Niosh N95 masks.

Prior to making the N95 mask purchase, the state researched Dasheng and determined the company had a long history in China and had been an exporter of N95 masks to the United States for decades. In addition, Dasheng is listed as an approved manufacturer of N95 masks by multiple federal agencies of the U.S. government. Dasheng is one of the world's largest mask manufacturers.

# N95 Grade Medical Protective Masks Market Exclusive Study Report by Top Key Players Vogmask, 3M, Cardinal Health, Honeywell, Shanghai Dasheng

04-13-2020 07:55 AM CET | Health & Medicine
Press release from: Big Market Research

*N95 Grade Medical Protective Masks*

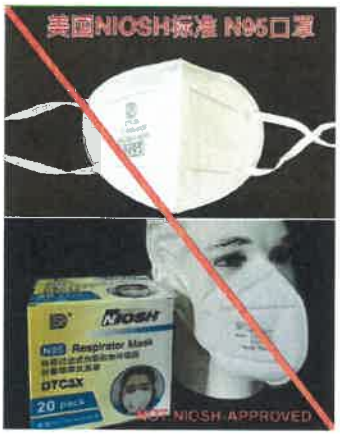
N95 respirators and surgical masks (face masks) are examples of personal protective equipment that are used to protect the wearer from airborne particles and from liquid contaminating the face. For example Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) also regulate N95 respirators masks. With the rising outbreak of the virus (Covid-19), people are indeed buying these masks as their PPE.

The N95 Grade Medical Protective Masks Market research report presents a comprehensive assessment of the market and contains thoughtful insights, facts, historical data and statistically-supported and industry-validated market data and projections with a suitable set of assumptions and methodology. It provides analysis and information by categories such as market segments, regions, and product type and distribution channels.

Request a sample of this premium research @:
https://www.bigmarketresearch.com/request-sample/3732071?utm_source=RK-OPR

By Market Players: 3M, Vogmask, Cardinal Health, Honeywell, Shanghai Dasheng, Kimberly-clark, CM, Ansell, KOWA, DACH, Hakugen, Gerson, Sinotextiles, Te Yin

Prominent players in the market:
- o 3M
- o Shanghai Dasheng
- o Honeywell
- o CardinalHealth
- o Ansell
- o Kimberly
- o CM
- o Hakugen
- o Gerson
- o DACH
- o Yuanqin
- o Winner




These are examples of counterfeit respirators using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval number, TC-84A-4329, without their permission. Please note these respirators have ear loops. The NIOSH-approved SDH model does NOT have ear loops. These respirators are not NIOSH approved. (3/31/2020)

The fire chief was referencing a March 3 advisory from the CDC that Dasheng N95 masks, among other brands, were being counterfeited:

During the period of April 10 to April 16, DMAPS performed due diligence regarding the possibility that the state had purchased counterfeit N95 masks. This due diligence included tracing the purchase through the following companies:

1. Ballard Safety Equipment, West Virginia
2. Downstream Recycling, South Carolina
3. USCH International Inc. a Texas LLC
4. Eastern 7 Enterprises, LLC, a Texas limited liability company

5. Shen Zhen Shi Ya Qi Technology Limited Company, a Chinese entity ("Ya Qi").
6. Beidahuang Limited Trading Company, a Chinese entity
7. Shanghai Dasheng Health Products Manufacture Company, Ltd

All companies have cooperated to date and the law firm of Hsiung & Associates and Diana C. Hsiung, attorney at law, of Houston, Texas provided the service of translation and assisted in obtaining various documents.

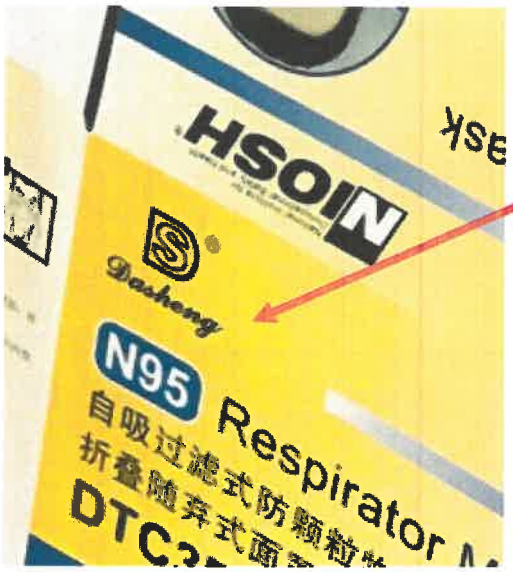
**Investigative steps taken:**

- Reviewed the packaging and product of our N95 masks.
- Contacted the West Virginia vendor and obtained their cooperation.
- Contacted and interviewed the East Coast vendor and obtained their cooperation.
- Contacted and interviewed the U.S. importer and obtained their cooperation.
- Contacted and interviewed, with prepared questions, the Chinese exporters through legal counsel in Houston, Texas and obtained their cooperation.
- Contacted the manufacturer in China through legal counsel in Houston, Texas and obtained their cooperation.

**Review of the packaging and product of our N95 masks.**

The investigation showed the N95 masks purchased by the state were in Dasheng's correct packaging. Dasheng agrees that the packaging referenced on the CDC website and shown below is counterfeit.

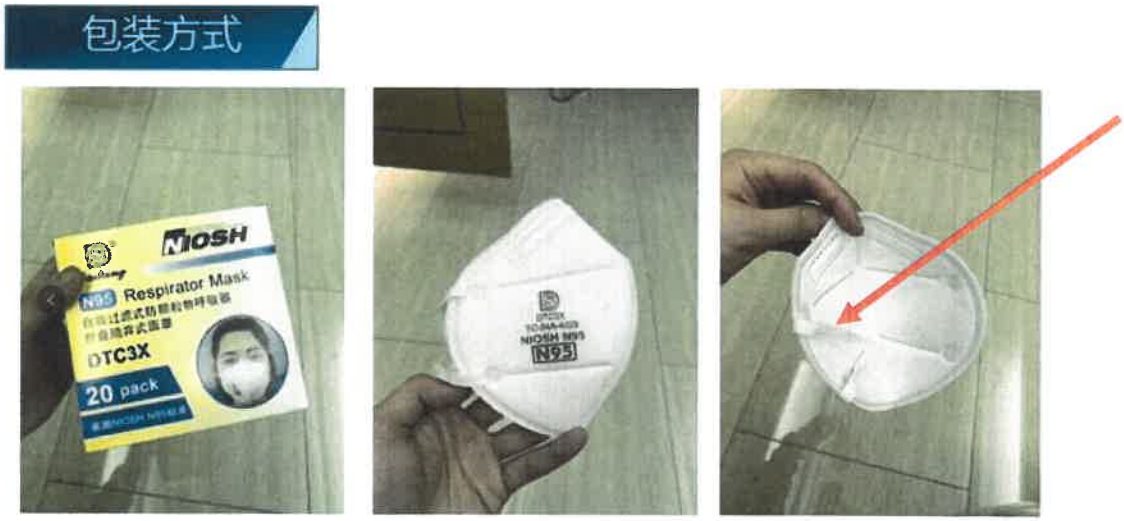

No "Dasheng" company name listed on counterfeit box on CDC announcement. No boxes like this were received by state.




Boxes received by the state matched and were validated as Dasheng boxes.

Communication from the CDC clearly state that NIOSH N95 masks that have ear loops are not NIOSH approved. However, the DMAPS investigation shows that the exporter into the United States did not attempt to cover up the fact that the DTC3X KN95 masks purchased had ear loops and provided multiple documents and photographs to support this fact. In addition, as stated above the DTC3X is a KN95 mask.

On April 15, 2020, the following information is from Dasheng's catalog which was obtained from the law firm of Hsiung & Associates that shows that Dasheng DTC3X mask with loops.



The Texas law firm was able to provide DMAPS with the following documentation showing the purchase of the masks.

深圳市雅祺科技有限公司文件

雅祺科技公司（2020）第 018 号　　签发人：李奕磊

购买证明

Eastern 7 Enterprise LLC.于 2020 年 3 月 24 日从我公司采购 100,000 个大胜品牌 N95 口罩，该批口罩有两种型号：DTC3X 及 DTC3B。 DTC3B 为头套式口罩，DTC3X 为耳挂式口罩，特此说明！

深圳市雅祺科技有限公司

地址：深圳市龙华区梅龙大道 2125 号上东龙湖大厦 1517

电话：+8615219477305 +86-0755-23777989

2020 年 4 月 15 号

CERTIFICATE OF TRANSLATION

I, Diana C. Hsiung, hereby certify that I am competent in both the Chinese and English language and that I have translated the attached document.

Diana C. Hsiung

***"Shen Zhen Shi Ya Qi Technology Limited Company Document***

***Ya Qi Technology Company***
***Signor: Yi Lei Li***
***Proof of Purchase***

***On March 24, 2020 Easter 7 Enterprises LLC acquired from our company 100,000 Dasheng brand N 95 masks, said acquired masks composed of two different models: DTC3X and DTC3B. DTC3B contains rear band, DTC3X contains ear loops, hereby clarify the same!***

***(Seal: Shen Zhen Shi Ya Qi Technology Limited Company)***

***Shen Zhen Shi Ya Qi Technology Limited Company***
***Address: Shen Zhen Shi, Long Hua District, Mei Long Blvd. No. 212, Business Tower 1517***
***Telephone: +8615218477305 +80 0755-23777989***

***April 15th, 2020"***

The below documents were also provided by Dasheng through the U.S. law firm of Hsiung and Associates, and its counsel Diana C. Hsiung located at 6100 Corporate Dr. Ste. 170, Houston, TX 77036, 713.988.6388.

大胜口罩国际认证一览表

Dasheng Mask Approved Schedule

认证总数 230 张 Total 230 approvals

CE0194

一、EN149: 2001+A1:2009 CE证书共133张 ( A total of 133 CE approvals )

FFP1 NR (48 types): DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C (dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3X(dolomite)、DTC3X-F(dolomite)、DTC2XS、DTC2XS-F、DTC3XS、DTC3XS-F、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4X(dolomite)、DAC4X-F(dolomite)、DAC3XS、DAC3XS-F、DAC4XS、DAC4XS-F、DAC4Z(dolomite)、DAC4Z-F(dolomite)

FFP2 NR (41 types): DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C (dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3X(dolomite)、DTC2X-F(dolomite)、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4X(dolomite)、DAC4X-F(dolomite)、DAC4Z(dolomite)、DAC4Z-F(dolomite)

FFP3 NR (41 types): DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C (dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3XD(dolomite)、DTC3XD-F(dolomite)、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4XD(dolomite)、DAC4XD-F(dolomite)、DAC4Z(dolomite)、DAC4Z-F(dolomite)

GOGGLE (2 types): DS 8810 (Grade F)、DS 8830 (Grade B)

二、AS/NZS1716: 2003 澳大利亚证书共52张(A total of 52 AS/NZS approvals)

P1 (25 types): DAC4、DAC4-F、DTC3B、DTC3B-F、DAC4B、DAC4B-F、DTC3M、DTC3M-F、DAC4M、DAC4M-F、DTC3X、DTC3X-F、DAC4X、DAC4X-F、DTCA1、DTCA1-F、DACA1、DACA1-F、DTCA1N、DTCA1N-F、DACA1N、DACA1N-F、DTC3Z、DTC3Z-F、DAC4Z、DAC4Z-F

P2 (26 types): DAC4、DAC4-F、DTC3B、DTC3B-F、DAC4B、DAC4B-F、DTC3M、DTC3M-F、DAC4M、DAC4M-F、DTC3X、DTC3X-F、DAC4X、DAC4X-F、DTCA1、DTCA1-F、DACA1、DACA1-F、DTCA1N、DTCA1N-F、DACA1N、DACA1N-F、DTC3Z、DTC3Z-F、DAC4Z、DAC4Z-F

三、NIOSH NIOSH N95 NIOSH N99 美国N95证书共30张(A total of 30 NIOSH N95 approvals) 美国N99证书共4张(A total of 4 NIOSH N99 approvals)

N95 (30 types): DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M-1、DTC3C-F、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTCA1N、DTCA1N-F、DTC3B、DTC3B-F、DTC3X、DTC3X-F、DAC4、DAC4-F、DAC4C、DAC4C-F、DAC4A、DACA1、DACA1-F、DAC4X、DAC4X-F、DAC4B、DAC4B-F、DTC3Z、DTC3Z-F

N99 (4 types): DTCA1、DTCA1-F、DTCA1N、DTCA1N-F

四、FDA FDA证书共3张 (A total of 3 FDA approvals)

3-ply facemask in white/ bule/ yellow/ pink/ green, DTC3B N95, DTC3M- 1N95

五、Japan Approved 日本DS2证书共8张 (A total of 8 DS2 approvals)

DF721 DF731 DF741 DF751 DF620 DF630 DF640 DI650

至2019年9月止 ( 其它还在认证中 ) As of SEP, 2019 (others applied)

DTC3B

DTC3X

In addition, the importer provided the following from the Chinese exporter advising the N95 masks purchased by West Virginia are "authentic."

深圳市雅祺科技有限公司文件

雅祺科技公司（2020）第 011 号　　签发人：李奕磊

购买证明

本公司是上海大胜卫生用品制造有限公司授权经销商。Eastern 7 Enterprise LLC. 于 2020 年 3 月 24 日从我公司采购 100,000 个大胜品牌口罩，该批口罩有两种型号：DTC3X 及 DTC3B。所有的口罩均为正品，从上海大胜工厂仓库直接提货，无质量问题，符合 N95 质量标准。

深圳市雅祺科技有限公司

地址：深圳市龙华区梅龙大道 2125 号卫[illegible]龙商务大厦 1517

电话：+8615219477305　+80 0755-23777989

2020 年[illegible]月 11 号

Translation to the above correspondence dated April 11, 2020

**CERTIFICATE OF TRANSLATION**

I, Diana C. Hsiung, hereby certify that I am competent in both the Chinese and English language and that I have translated the attached document.

Diana C. Hsiung

Shen Zhen Shi Ya Qi Technology Limited Company Document

Ya Qi Technology Company
Signor: Yi Lei Li

Proof of Purchase

Our Company is the distributor for Shanghai Da Shen Health Goods Production Limited Company. Eastern 7 Enterprise LLC purchased from our company 100,000 Da Sheng brand face mask which include two variations: DTC3X and DTC3B. All masks are authentic and was tendered to us at Shanghai Da Sheng's factory warehouse with no issue regarding its quality and compliance with N95 standard.

(Seal :Shen Zhen Shi Ya Qi Technology Limited Company)

Shen Zhen Shi Ya Qi Technology Limited Company
Address:Shen Zhen Shi, Long Hua District, Mei Long Blvd. No. 212, Business Tower 1517
Telephone: +8615218477305 +80 0755-23777989

April 11th, 2020

产品介绍

# “大胜”N95产品手册


【品名】N95无阀口罩

【执行标准】GB 2626-2006

【规格】随弃式面罩，无呼吸阀

【适用范围】供各类人员在非有创操作过程中佩带，为防止病毒、细菌等病原体微生物、颗粒物等的直接透过提供一定的物理屏障。

【出口】可出口，美国FDA认证，欧盟CE认证：EN149

**Federal Assistance**

The CDC and FDA assisted DMAPS in the investigation by providing support and information to provide this overview to our state's first responders. The FDA provided assistance as follows:

https://www.fda.gov/media/136664/download

On April 3, 2020, in response to this evolving public health emergency and continued concerns about filtering facepiece respirator (FFR) 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. (Page 1 paragraph 2)

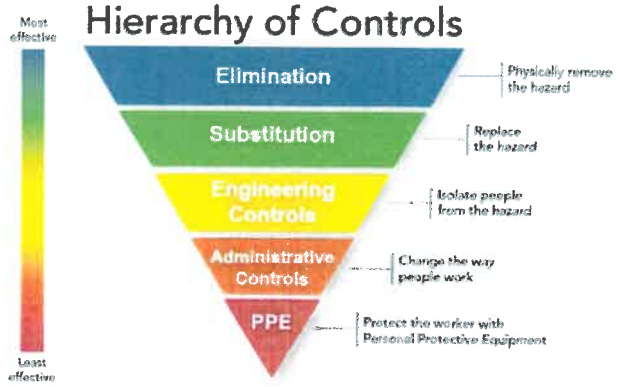
The FDA also published a list of N95 respirators made in China that are “authorized respirators” which includes the masks purchased by the state.

| | | |
|---|---|---|
| Shanghai Dasheng Health Products Manufacture Company, Ltd. | DTC3X-1, DTC3X-2, DTC3X-3, DTC3B-1 | China |

**Conclusion**

It should be noted that the use of PPE is important but other factors are even more important for our states first responders as illustrated by the CDC in the picture to the right.

The CDC stresses the importance of a proper fit when wearing a respirator with ear loops, to ensure it provides the designed level of protection.



https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-and-cdc-take-action-increase-access-respirators-including-n95s

As Cabinet Secretary, I assure you that as I have been for the past 40 years, I am here for all of you during this war, and I am proud that the state allowed us to purchase the masks that you have been provided. As I stated to you on April 15, 2020, we worked around the clock to get you protection as soon as possible. I feel todate it has done its job.

Thanks to all of you first responders!

**Appendix A: Authorized Respirators**
*Updated: April 17, 2020*

**The Authorized Respirators**

Authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

**Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China**

| Manufacturer | Respirator Model(s) | Country of Manufacture |
|---|---|---|
| 3M | 9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V | China |
| AAB (China) Co., Ltd. | KN95 | China |
| Allmed | KN95 Particulate Respirator LP220002 | China |
| Anhui Zhongke Duling Commercial Appliance Co., Ltd | Mether M-9501 EN149:2001 FFP2 | China |
| Anshun Health and Medical Technology Co., LTD | AKF2002 | China |
| AOK Tooling Ltd. (aka Shenzhonghai Medical) | 20130040, 20130045A, 20180021, 20130038, 20190019 | China |
| Bei Bei Safety Co Ltd. | B702, B702V, B704, B704V | China |

| | | |
|---|---|---|
| Bei Bei (Dong Shan) Protective Supplies Co., LTD | B707 | China |
| BYD Precision Manufacture Co. Ltd. | BYD KN95 Particulate Respirator<br>(Model Number: DG3101) | China |
| Changsha JNEYL Medical Equipment Co., Ltd | JN-9501 | China |
| Changzhou Wedream Medical Device Co., Ltd | KN95 | China |
| Chengde Technology Co. | KN95 (PM 2.5) Protective Mask | China |
| China Nano Technology Co., Ltd | ZN6005<br>ZN8005 | China |
| Chongqing China Nano Technology Co., Ltd. | KN95 ZN6005 | China |
| Chongqing Zaisheng Technology Co., Ltd. | ZS-A950 | China |
| Chuzhou Qiao Dong Industrial Co., Ltd | Langie KN95 FFP2 | China |
| Creative Concepts Manufacturing Ltd | 02669, 02676, KN95 | China |
| CTT CO. Ltd. | KN95 | China |
| Daddybaby Co. Ltd. | KN95 FFP2 | China |

| | | |
|---|---|---|
| Dongguan Arun Industrial Co., LTD | KN95 N9 | China |
| DongGuan HuaGang Communication Technology Co., Ltd | KN95-A; KN95-B | China |
| Dongguan Leihuo Medical Device Co., LTD | CPFM-100, CPFM-101, LH-KN95 | China |
| Dongguan Sengtor Plastics Products Co., Ltd. | KN95 | China |
| Dongguan Xianda Medical Equipment Co., Ltd | KN95 | China |
| Foshan Nanhai Weijian Sanbang Protective Equipment Technology Co., Ltd | KN95 Model 9051A | China |
| Fujian Kang Chen Daily Necessities Co, Ltd. | K0450, 57793 | China |
| Fujian Pageone Garment Co., Ltd | KN95 | China |
| Fujian Yongtai Sanlian Garment Co., Ltd. | N95 | China |
| Guangdong Fei Fan MStar Technology Ltd. | KN95 | China |

| | | |
|---|---|---|
| Guangdong Golden Leaves Technology Development Co., Ltd. | 8862 KN95 | China |
| Guangzhou Aiyinmei Co., LTD | A&F KN95 | China |
| Guangzhou Harley Commodity Company Limited | L-103V KN95 | China |
| Guangzhou Improve Medical Instruments Co., LTD | PPDS N95 Respirator and Surgical Mask Model No. PPDS Ear Hook M | China |
| Guangzhou Nan Qi Xing Nonwoven Co. Ltd | KN95 | China |
| Guangdong Nuokang Medical Technology Co., Ltd. | KN95 | China |
| Guangzhou Powecom Labor Insurance Supplies Co., LTD | KN95 | China |
| Guangzhou Sunjoy Auto Supplies Co., LTD | Earhook folding type K1-K100<br>Headband folding type K1-K100 | China |
| Guangdong Kaper Protection Technology Co., Ltd | KP-K02 (N95) | China |

| | | |
|---|---|---|
| Guangdong ZhiZhen Biological Medicine Co., LTD | KN95 | China |
| Guangzhou Yihere Medical Technology Development Co., Ltd. | YH-MFK-B95, YH-MFK-Z95 | China |
| Guizhou Bocai Medical Device Co., Ltd. | Bocai KN95 | China |
| HeiQ Materials AG | HVB-FFP2-01 | China |
| Henan Fengzhihuang Industrial Co., Ltd | HF/KN95-3 | China |
| Henan Youmaisi Health Technology Co. LTD | YMS-AN95 | China |
| Huizhou Green Communication Equipment Manufacturing Co., Ltd | G95200 | China |
| Huizhou Huinuo Technology Co., LTD | HV-N White 9501A, HV-N White 9501B | China |
| Huizhou Jiahe Cubic Technology Co., LTD | KN95 | China |
| Huizhou Lexuslance Technology Co. Ltd | LK-003 | China |

| | | |
|---|---|---|
| Improve Medical (Hunan) Co. Ltd. | PPDS Strap Headband M<br>PPDS Ear Hook M | China |
| Jiangsu Weichuangli New Materials Co., Ltd. | WCL-0075 | China |
| Jiangsu Yimao Filter Media Co., Ltd | 9570K | China |
| Jiangxi Hornet Industrial Co. Ltd. | S-KN95 | China |
| Jiangxi Yifengyuan Biological Engineering Co., Ltd. | N95, KN95 | China |
| Jinhua Jiadaifu Medical Supplies Co. Ltd | KN95 FFP2 | China |
| Jinan Vhold Co., LTD | VH-95 | China |
| Juntech (Jiaxing) Healthcare Materials Co. Ltd | KN95 | China |
| Lanshan Shendun Technology Co. | SD-KN95-01, SD-KN95-02, SD-KN95-C01, SDKN95-C02 | China |
| Panzhihua Gangcheng Group Yasheng Industrial Co., Ltd. | KN95 | China |
| Qingdao Orphila Medical | OM-KN95-FFP2 | China |

| | | |
|---|---|---|
| Technology Co. LTD. | | |
| Qingyuan Leite Technology Development Co. | GV-0095A, GVHKN95 | China |
| Raxwell Industrial Technology (Shanghai) Co., Ltd. | RX9501 | China |
| Rizhao Sanqi Medical & Health Articles Co., Ltd | RIZ100CVb, 3Q KN95, 3Q FFP2 NR, RIZQ100Sb, 3Q KN95 9505 | China |
| Shandong Daddy's Choice Health Science and Technology Co., Ltd | Purism KN95 | China |
| Shandong Huishoutang Pharmaceutical Co | KN95 | China |
| Shandong Shengquan New Material Co., Ltd | SNN70370B (Willow leaf form valveless) | China |
| Shanghai Dasheng Health Products Manufacture Company, Ltd. | DTC3X-1, DTC3X-2, DTC3X-3, DTC3B-1 | China |
| Shanghai Yunqing Industrial Co.,Ltd. | YQD95 KN95 | China |
| Shauguan Taijie Protection | KN95 | China |

| | | |
|---|---|---|
| Technology Co. Ltd. | | |
| Shenzhen Horb Technology Corp., Ltd | 1.7.02.02.0001 | China |
| Shenzhen Missadola Technology Co., Ltd, dba 1AK Medical Supplies | 2626-1 KN95 | China |
| Sunright Medical Technology (GuangDong) Co., LTD | KN95-C3 | China |
| Suzhou Bolisi Medical Technology Co., Ltd | BS-9501L, BS-9501FL, BS-9502C, BS-9502FC | China |
| Suzhou Sanical Protective Product Manufacturing Co., Ltd | Model 8015, Model 9015 | China |
| Tianjin Benmo Medical Equipment Co., Ltd. | KN95 | China |
| Weini Technology Development Co., Ltd | FFP2 NR E-300, FFP2 NR E-680, FFP2 NR 952, FFP2 NR F-820, KN95 958, KN95 951 | China |
| Winner Medical Co. Ltd. | WN-N95FW, WN-N95FG, WN-N95FGIN | China |
| Yiwu Henghao household products Co., Ltd | HH-KN95-001 | China |

| | | |
|---|---|---|
| Yiwu Yifan Knitting Co. Ltd | KN95 | China |
| Zhangzhou Easepal Industrial Corp. | MASK-104 | China |
| Zhejiang Baiyi Intelligent Garment Co LTD | KN95 | China |
| Zhejiang Shengtai Baby Products Co Ltd | KN95 | China |
| Zhende Medical Co., LTD | N9501F | China |
| Zhengzhou QBS New Material Co., LTD | KN95 | China |
| Zhengzhou Ripe Medical Technology Co., LTD | Disposable Protective Mask KN95 | China |
| Zhengzhou Ruipu Medical Technology Co.,Ltd | KN95 | China |
| Zhengzhou Wanshenshan Healthcare PPE Co., Ltd. | KN95 | China |
| ZhongKang protective equipment technology (Guangzhou) Co., Ltd | ZK601 | China |

HOMELAND SECURITY INVESTIGATIONS

# HSI

# S.T.O.P. COVID-19 FRAUD

## STRATEGIC TARGETED OUTREACH PROGRAM

**Recognize • Protect • Report | COVID-19 Crime**

## ONLINE SHOPPING RED FLAGS FOR MARKETPLACE AND WEBSITES

- DO NOT CLICK ON UNSOLICITED EMAILS OR TEXTS.
- ENSURE A SECURE BROWSER CONNECTION: HTTPS ONLY.
- VERIFY WEBSITE TRUST SEALS BEFORE PLACING AN ORDER.
- OFFICIAL U.S. GOVERNMENT WEBSITES END IN .GOV
- INSPECT THE URL OF THE WEBSITE AND VERIFY THE DESTINATION.

## FINANCIAL RED FLAGS RELATED TO COVID-19

- BEWARE OF E-MAILS, TEXT MESSAGES OR CALLS OFFERING GOODS, SERVICES, LOANS, OR DEBT RELIEF.
- BEWARE OF REQUESTS FOR UNUSUAL PAYMENT METHODS, SUCH AS CRYPTOCURRENCY, PREPAID DEBIT CARDS, GIFT CARDS, MONEY SERVICE BUSINESSES (MSB) TRANSFERS, OR WIRE TRANSFERS.
- GOVERNMENT AGENCIES DO NOT CALL, TEXT OR E-MAIL: CHECK YOUR MAIL, DO NOT FOLLOW LINKS ON SOCIAL MEDIA, AND UTILIZE GOVERNMENT WEBSITES DIRECTLY.
- GOVERNMENT AGENCIES WILL NOT CALL OR E-MAIL ABOUT ECONOMIC IMPACT PAYMENTS AND WILL NOT REFER TO IT AS "STIMULUS" – DO NOT OPEN SUCH E-MAILS OR CLICK ON ATTACHMENTS.

## PROHIBITED PHARMACEUTICALS AND MEDICAL DEVICES RED FLAGS

- BEWARE OF WEBSITES OR INDIVIDUALS SELLING PRODUCTS ALLEGING THEY CAN PREVENT, TREAT, DIAGNOSE OR CURE COVID-19.
- CURRENTLY, NO COVID-19 TEST KITS ARE AUTHORIZED FOR PRIVATE SALE TO INDIVIDUALS. AUTHORIZED COVID-19 TEST KITS ARE ONLY BEING DISTRIBUTED TO MEDICAL PROFESSIONALS.
- BEWARE OF PHARMACEUTICAL PRODUCT INFORMATION WRITTEN IN A FOREIGN LANGUAGE OR WITH MISSPELLINGS.
- DON'T BUY PRESCRIPTION PHARMACEUTICALS FROM THIRD PARTY MARKETPLACES OR SOCIAL MEDIA PLATFORMS.

## DID YOU KNOW?

Thousands of COVID-19 related web domains have been identified as fraudulent.

Government agencies will not contact anyone to verify a payment was made or to expedite payments.

Consumers interested in finding out if a COVID-19 related product or website is "real or fake," can #AskGTI on Twitter @IPRCenter

## ONLINE SHOPPING TIPS

- IF A DEAL SEEMS TOO GOOD TO BE TRUE, IT PROBABLY IS.
- BE AWARE OF PRICE GOUGING.
- VERIFY PURCHASES ARE FROM LEGITIMATE, TRUSTED SOURCES.
- REPORT COVID-19 FRAUD TO COVID19FRAUD@DHS.GOV.

## FINANCIAL TIP

$ REACH OUT TO YOUR ELDERLY FRIENDS AND FAMILY MEMBERS AND WARN THEM ABOUT THESE SCAMS.

## PROHIBITED ITEMS TIP

- ENSURE YOUR ONLINE PHARMACY IS CERTIFIED BY CHECKING: WWW.SAFEMEDSONLINE.ORG.

FOR MORE INFORMATION PLEASE VISIT
WWW.ICE.GOV

REPORT COVID-19 FRAUD TO
COVID19FRAUD@DHS.GOV

REPORT FRAUD

**Sandy, Jeff**

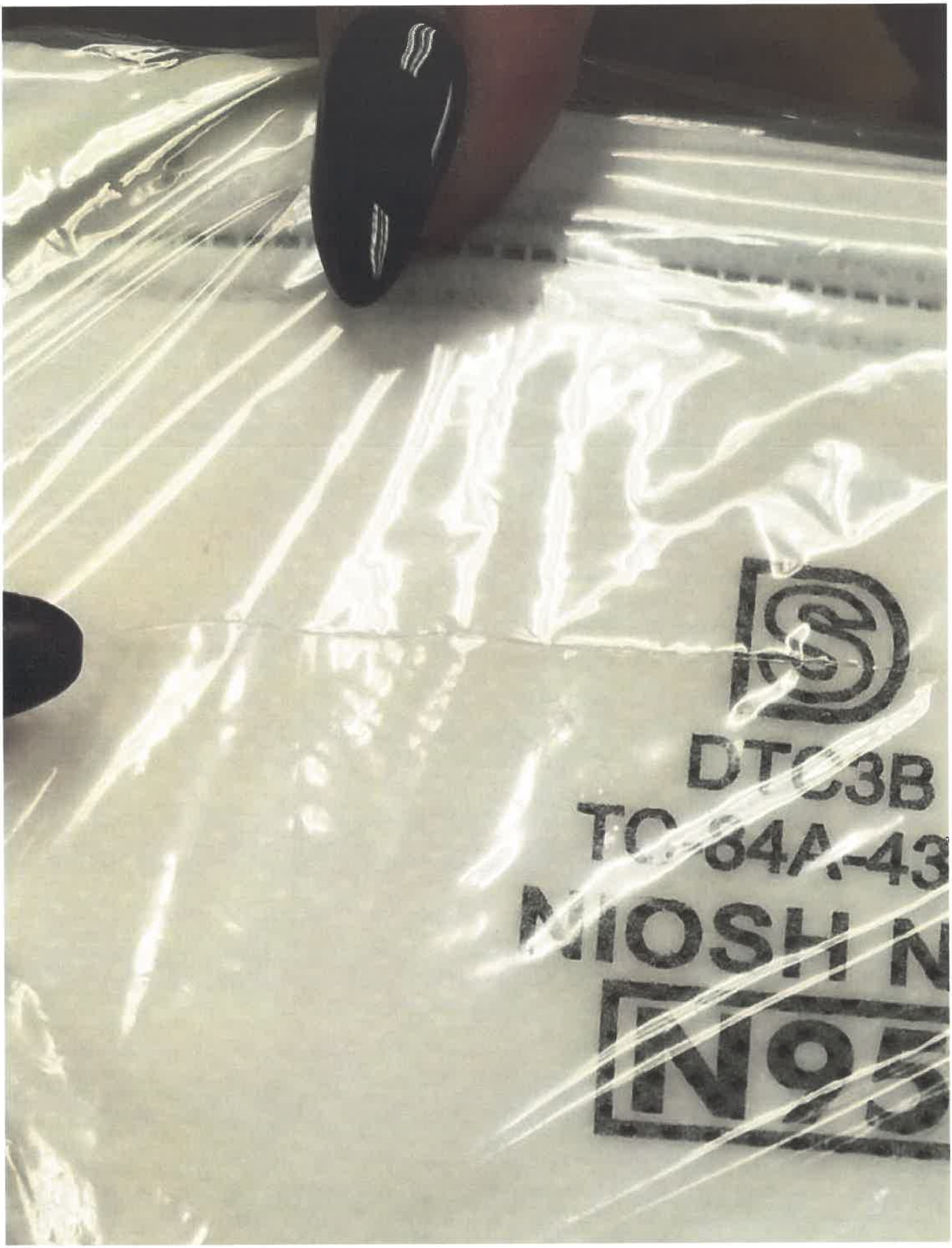
**From:** Clendenin, Shana M
**Sent:** Friday, April 10, 2020 3:45 PM
**To:** Sandy, Jeff
**Subject:** FW: [External] FW: Counterfeit PPE

Shana M. Clendenin, Operations Officer
WV Division of Homeland Security and Emergency Management
1703 Coonskin Dr.
Charleston, WV 25311
Office Phone: 304-414-7642
Cell Phone: 304-389-1263
Home Phone: 304-675-1919

*"There are risks and costs to action. But they are far less than the long-range risks of comfortable inaction" – J.F. Kennedy*



**From:** Chris Mcintire <cmcintire@marioncountywv.com>
**Sent:** Friday, April 10, 2020 3:25 PM
**To:** Clendenin, Shana M <Shana.M.Clendenin@wv.gov>
**Subject:** Re: [External] FW: Counterfeit PPE


DT
3B
TC
64A-43
MIOSH N
NO

Yes. Is what we picked up

Get Outlook for Android

---

**From:** Clendenin, Shana M <Shana.M.Clendenin@wv.gov>
**Sent:** Friday, April 10, 2020 3:12:45 PM
**To:** Chris Mcintire <cmcintire@marioncountywv.com>
**Subject:** RE: [External] FW: Counterfeit PPE

Can you send me a picture of what you received? Also... just to be clear, this is what was delivered and picked up from DMAPS at the capitol correct?

Shana M. Clendenin, Operations Officer
WV Division of Homeland Security and Emergency Management
1703 Coonskin Dr.
Charleston, WV 25311
Office Phone: 304-414-7642
Cell Phone: 304-389-1263
Home Phone: 304-675-1919

*"There are risks and costs to action. But they are far less than the long-range risks of comfortable inaction" - J.F. Kennedy*

**From:** Chris Mcintire <cmcintire@marioncountywv.com>
**Sent:** Friday, April 10, 2020 3:10 PM
**To:** Clendenin, Shana M <Shana.M.Clendenin@wv.gov>
**Subject:** [External] FW: Counterfeit PPE

CAUTION: External email. Do not click links or open attachments unless you verify sender.

We received the yellow boxes from the State for Police and Fire. (240 mask to Marion) Look on the CDC counterfeit list 3rd section down yellow with Chinese writing.

**From:** Ed Simmons
**Sent:** Friday, April 10, 2020 2:52 PM
**To:** Chris Mcintire <cmcintire@marioncountywv.com>
**Subject:** Counterfeit PPE

Chris,

I'm sure that you are aware, but just in case.
https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

I just got off a video conference with the Professional Fire Chiefs of WV and the state distributed several counterfeit N95s to the various county 911 directors. I do not know the extent throughout the rest of the state.

Chief Ed Simmons
Fairmont Fire Department
500 Quincy Street
Fairmont, WV 26554
(Office)304-363-7620
(Cell)304-694-4382
(Fax)304-368-2654
Email- esimmons@fairmontwv.gov

**Sandy, Jeff**

| | |
|---|---|
| **From:** | Sandy, Jeff |
| **Sent:** | Wednesday, April 15, 2020 12:49 PM |
| **To:** | Gavel, Kim C. (CDC/NIOSH/NPPTL/ETB) |
| **Cc:** | Kirk, Thomas L; Powers, John R. (CDC/NIOSH/NPPTL/ETB); Kirk, Thomas L |
| **Subject:** | RE: Additional Assistance |

Ms. Gavel;

I know we are all very busy and I appreciate your information. The attached documents may be of interest to you.

**深圳市雅祺科技有限公司文件**

雅祺科技公司〔2020〕第018号　　签发人：李奕磊

**购买证明**

Eastern 7 Enterprise LLC.于 2020 年 3 月 24 日从我公司采购 100,000 个大胜品牌 N95 口罩，该批口罩有两种型号：DTC3X 及 DTC3B。 DTC3B 为头套式口罩，DTC3X 为耳挂式口罩，特此说明！

深圳市雅祺科技有限公司

地址：深圳市龙华区梅龙大道 2125 号 [illegible] 1517

电话：+8615219477305 +86 0755-23777989

2020 年 4 月 15 号

*"Shen Zhen Shi Ya Qi Technology Limited Company Document*

*Ya Qi Technology Company*
*Signor: Yi Lei Li*
*Proof of Purchase*
*On March 24, 2020 Easter 7 Enterprises LLC acquired from our company 100,000 Dasheng brand N 95 masks, said acquired masks composed of two different models: DTC3X and DTC3B. DTC3B contains rear band, DTC3X contains ear loops, hereby clarify the same!*
*(Seal: Shen Zhen Shi Ya Qi Technology Limited Company)*

*Shen Zhen Shi Ya Qi Technology Limited Company*
*Address: Shen Zhen Shi, Long Hua District, Mei Long Blvd. No. 212, Business Tower 1517*
*Telephone: +8615218477305 +80 0755-23777989*

*April 15th, 2020"*

深圳市雅祺科技有限公司文件

[illegible]公司（2020）第011号　　签发人：李雅磊

购买证明

本公司是上海大胜卫生用品制造有限公司授权经销商。Eastern 7 Enterprise LLC. 于 2020 年 3 月 24 日从我公司采购 100,000 个大胜品牌口罩，该批口罩有两种型号：DTC3X 及 DTC3B。所有的口罩均为正品。从上海大胜工厂仓库直接提货，无质量问题，符合 N95 质量标准。

深圳市[illegible]科技有限公司

地址：深圳市龙华区梅龙大道 2135 号[illegible]1517

电话：+8615218477305　+80 0755-23777989

2020 年 4 月 11 号

Shen Zhen Shi Ya Qi Technology Limited Company Document

Ya Qi Technology Company
Signor: Yi Lei Li

Proof of Purchase

Our Company is the distributor for Shanghai Da Shen Health Goods Production Limited Company. Eastern 7 Enterprise LLC purchased from our company 100,000 Da Sheng brand face mask which include two variations: DTC3X and DTC3B. All masks are authentic and was tendered to us at Shanghai Da Sheng's factory warehouse with no issue regarding its quality and compliance with N95 standard.

(Seal :Shen Zhen Shi Ya Qi Technology Limited Company)

Shen Zhen Shi Ya Qi Technology Limited Company
Address:Shen Zhen Shi, Long Hua District, Mei Long Blvd. No. 212, Business Tower 1517
Telephone: +8615218477305 +80 0755-23777989

April 11th, 2020

**Jeff S. Sandy, CAMS, CFE**
***Cabinet Secretary***
**Department of Military Affairs and Public Safety**
**State Capitol Complex Room W-400**
**1900 Kanawha Boulevard East**
**Charleston, WV 25305**
304-558-2930 (office)
304-553-6826 (cell)

**From:** Gavel, Kim C. (CDC/NIOSH/NPPTL/ETB) <kgc5@cdc.gov>
**Sent:** Wednesday, April 15, 2020 12:46 PM
**To:** Sandy, Jeff <Jeff.Sandy@wv.gov>
**Cc:** Kirk, Thomas L <Thomas.L.Kirk@wv.gov>; Powers, John R. (CDC/NIOSH/NPPTL/ETB) <jop5@cdc.gov>; Kirk, Thomas L <Thomas.L.Kirk@wv.gov>
**Subject:** RE: Additional Assistance

Mr. Sandy,

The information and photos of the products you provided indicate that these products are KN95s claiming to meet the GB2626-2006 standard, which is the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator. Products claiming to meet GB26526 should have a filter efficiency of at least 95%. However, we have received and tested limited samples of other products claiming to meet the GB2626 standard that are less than 95%.

For respirators that have ear loops it is important to ensure that the respirator has proper fit to ensure it provides the level of protection it was designed for. Therefore, we highly recommend that each person that will be wearing these respirators check the fit prior to using them. You can check the fit by following these instructions. If there are large gaps where the mask comes in contact with your face, try to adjust the straps so the mask fits tighter against the face.

The CDC issued crisis capacity strategies and FDA issued guidance for the use of respirators from other countries. We do not have test data for these products, so we cannot tell you if they provide the protection required by the GB2626 standard. For non NIOSH-approved products that claim to meet an international standard, we are currently offering to conduct testing. If you are interested in having any of these units tested, information on this testing can be found at the following link: International Respirator Assessment Request.

As we do more and more testing of these international products, we will be sharing the results with the FDA to make adjustments to the products listed in the Emergency Use Authorization (EUA).

Kind regards,
Kim Gavel

**From:** Sandy, Jeff <Jeff.Sandy@wv.gov>
**Sent:** Wednesday, April 15, 2020 9:15 AM
**To:** Gavel, Kim C. (CDC/NIOSH/NPPTL/ETB) <kgc5@cdc.gov>
**Cc:** Kirk, Thomas L <Thomas.L.Kirk@wv.gov>; Powers, John R. (CDC/NIOSH/NPPTL/ETB) <jop5@cdc.gov>; Kirk, Thomas L <Thomas.L.Kirk@wv.gov>
**Subject:** RE: Additional Assistance

CDC Leaders;

Do you feel you can get me the answers to the below questions today?

**Jeff S. Sandy, CAMS, CFE**
***Cabinet Secretary***
**Department of Military Affairs and Public Safety**
**State Capitol Complex Room W-400**
**1900 Kanawha Boulevard East**
**Charleston, WV 25305**
304-558-2930 (office)
304-553-6826 (cell)

**From:** Sandy, Jeff
**Sent:** Tuesday, April 14, 2020 8:32 AM
**To:** Gavel, Kim C. (CDC/NIOSH/NPPTL/ETB) <kgc5@cdc.gov>
**Cc:** Kirk, Thomas L <Thomas.L.Kirk@wv.gov>; Powers, John R. (CDC/NIOSH/NPPTL/ETB) <jop5@cdc.gov>; Kirk, Thomas L <Thomas.L.Kirk@wv.gov>
**Subject:** RE: Additional Assistance

Chief and Deputy Chief;

I appreciate your correspondence, and I have some follow-up questions. Also, I want to provide your team with the alleged Dasheng invoice.

My office has distributed 50,000 masks to 1st responders in every West Virginia County. My questions are as follows:

1) Have the masks we received with the ear loops that have been issued to our 1st responders provided them with protection even if they are not NIOSH grade?
2) Would they have protected West Virginia 1st responders since March 23rd from COVID 19 better than a loose fit surgical mask?
3) Next question, if they not NIOSH approved will they protect the same as the following approved by FDA? I received this by email.

***"On April 3, 2020 the FDA published a list N95 respirators made in China that are "authorized respirators…authorized for use in healthcare settings by healthcare personnel when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates".***

***Some of the N95 and KN95 respirators have headbands but about half have earloops.***

***Below are examples from 5 different companies of FDA authorized respirators with earloops (please refer to Appendix A from the FDA Letter):"***

**3M 9001**


https://www.3mphilippines.com.ph/3M/en_PH/company-ph/all-3m-products/~/3M-Particulate-Respirator-9001-FFP1-500-EA-Case/?N=5002385+8711017+3292064810&rt=rud

**3M 9501**


http://www.icstation.com/9501-face-mask-anti-virus-kn95-protective-respirator-anti-particulate-pm25-dust-pollen-allergy-safety-face-mask-p-14609.html

**PPDS N95** from Improve Medical (Hunan) Co. Ltd.

https://improve-med.com/impromask

**Purism KN95** by Shandong Daddy's Choice Health Science and Technology Co. Ltd


https://purismtech.com/collections/products/products/branded-kn95-20-pcs-face-mask-respirator-4-layer-structure-personal-protection-anti-bacteria-anti-virus-anti-pollution-disposable-mask

**RX9501 Raxwell KN95**


http://www.raxwell.cn/en_US/page/catalog

**2626 KN95** by 1AK Medical Supplies


I received this by email that has not been translated, but was told it was the invoice that purchased these masks from Dasheng.

# N95口罩采购合同

甲方：北大荒（广州）贸易有限公司

乙方：上海大胜卫生用品制造有限公司

甲、乙双方根据《中华人民共和国合同法》及相关法律、法规之规定，本着友好合作、协商一致的原则，就甲方向乙方采购大胜牌 DHSH N95 口罩，达成协议如下：

一、订购要求

1.1 甲方向乙方订购口罩的品类如下：

| 类别 | 商品名称 | 规格型号 | 单价 | 个数 | 大小写金额 |
|---|---|---|---|---|---|
| 产品 | N95 | DHSH<br>10 85A 1329 | [redacted] | 1000万个 | [redacted]整 |
| 备注 | 1、甲方运费自付。2、含发票。<br>3、供货周期：30日每天不少于300万个 | | | | 含税 [redacted] |

1.2 乙方向甲方的交货时间以及批次：　　交货地点上海

| 日期 | 出货量（单位：万） | 日期 | 出货量（单位：万） |
|---|---|---|---|
| [redacted] | 每天不少于30万个 | | |
| 合同签订后根据日期会争取提前交货。 | | | |

二、付款条件

2.1

2.1 双方同意，甲方在签订合同的当天内向乙方付款支付订单总价的30%定金，之后甲方安排工厂排期，根据排期发货。

2.2 双方同意，如果甲方签完合同后未向乙方按本合同约定付款，则甲方违约，甲方需向乙方赔付违约金为总货款的5%，同时乙方有权单独取消本合同，并要求甲方承担违约责任。

Thanks in advance!

**Cabinet Secretary Jeff S. Sandy, CAMS, CFE**
West Virginia Department of Military Affairs and Public Safety
304-553-6826

2017 2015 2009 1980

*"Proud of our Past - Focused on our Future"*

**From:** Gavel, Kim C. (CDC/NIOSH/NPPTL/ETB) <kgc5@cdc.gov>
**Sent:** Monday, April 13, 2020 5:23 PM
**To:** Sandy, Jeff <Jeff.Sandy@wv.gov>
**Cc:** Kirk, Thomas L <Thomas.L.Kirk@wv.gov>; Powers, John R. (CDC/NIOSH/NPPTL/ETB) <jop5@cdc.gov>
**Subject:** RE: Additional Assistance

Mr. Sandy,

We are looking into this issue based on numerous inquiries we have received. Although I cannot tell you whether or not the units in your photos are counterfeit, I can tell you that they are not NIOSH-approved. All of Shanghai Dasheng's NIOSH approvals are for respirators that are secured to the face by a headband, not ear loops.

Currently we are receiving conflicting information about what is being sold directly from the Dasheng factory. Dasheng has told us that their product has been counterfeited, but at the same time we are receiving reports of product being purchased directly from the Dasheng factory that is labeled NIOSH-approved and has ear loops. If the product is not counterfeit, the fact that it has ear loops makes in not compliant with their NIOSH approval.

I am sorry that I don't better news or know more to tell you at this time. I will follow-up with you if we get more information. In the meantime, thank you for the additional information you provided, it may be useful to our investigation into this issue.

Kind regards,

***Kim C. Gavel***
*Deputy Chief, Evaluation and Testing Branch*
*National Personal Protective Technology Lab*
*phone: 412-386-5030*
*email: KGavel@cdc.gov*

**From:** Powers, John R. (CDC/NIOSH/NPPTL/ETB) <jop5@cdc.gov>
**Sent:** Monday, April 13, 2020 4:56 PM
**To:** Sandy, Jeff <Jeff.Sandy@wv.gov>
**Cc:** Kirk, Thomas L <Thomas.L.Kirk@wv.gov>; Gavel, Kim C. (CDC/NIOSH/NPPTL/ETB) <kgc5@cdc.gov>
**Subject:** RE: Additional Assistance

Mr. Sandy,

I have forwarded your message to my Deputy Branch Chief, Ms. Kim Gavel (CC'd on this message). Kim has been attempting to confirm the counterfeit issues with them.

We have been overrun with inquiries about Shanghai Dasheng. We are attempting to assist everyone with this issue as best we can.


## John R. Powers, Jr.

Chief, Evaluation and Testing Branch
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health

1000 Frederick Lane
Morgantown, WV 26508

Office: (304) 285-6219
Mobile: (304) 282-2274
Fax: (404) 471-2943

jpowers@cdc.gov


**From:** Sandy, Jeff <Jeff.Sandy@wv.gov>
**Sent:** Monday, April 13, 2020 4:44 PM
**To:** Powers, John R. (CDC/NIOSH/NPPTL/ETB) <jop5@cdc.gov>
**Cc:** Kirk, Thomas L <Thomas.L.Kirk@wv.gov>
**Subject:** Additional Assistance

Chief Powers;

I saw your email with Ms. Clendenin today which is below:

Shanghai Dasheng (SDH) is a NIOSH approval holder, and the models approved can be viewed on the NIOSH Certified Equipment List. All NIOSH approvals manufactured by SDH have headbands, not ear loops. This is why NIOSH suspected this to be a counterfeit product. We have been in communication with SDH and they have informed us that their products are being counterfeited, and we are reaffirming that information on the Buyer Beware section of our Respirator Trusted-Source Information webpage.

We would also like to point out that we recently performed the OSHA Quantitative Fit Test with a respirator with ear loops. The highest fit factor achieved was 11. The OSHA requirement is 100. Therefore, even if this respirator has an acceptable filter efficiency level, it is doubtful that the product would provide the level of protection expected, due to the poor fit.


## John R. Powers, Jr.

Chief, Evaluation and Testing Branch
National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health

1000 Frederick Lane
Morgantown, WV 26508

Office: (304) 285-6219
Mobile: (304) 282-2274
Fax: (404) 471-2943

jpowers@cdc.gov

Over the weekend I had communications with China representatives using an Attorney in Houston Texas as an interpreter. The Exporter advised the following which was translated into English. I have the Chinese version if you would like it.

Ya Qi Technology Company
Signor: Yi Lei Li

Proof of Purchase

Our Company is the distributor for Shanghai Da Shen Health Goods Production Limited Company. Eastern 7 Enterprise LLC purchased from our company 100,000 Da Sheng brand face mask which include two variations: DRC3X and DTC3B. All masks are authentic and was tendered to us at Shanghai Da Sheng's factory warehouse with no issue regarding its quality and compliance with N95 standard.

(Seal :Shen Zhen Shi Ya Qi Technology Limited Company)

Shen Zhen Shi Ya Qi Technology Limited Company
Address:Shen Zhen Shi, Long Hua District, Mei Long Blvd. No. 212, Business Tower 1517
Telephone: +8615218477305 +80 0755-23777989

April 11th, 2020

They also supplied the following photographs.

包装方式



产品介绍

# “大胜” N95产品手册

【品名】N95无阀口罩

【执行标准】GB 2626-2006

【规格】随弃式面罩，无呼吸阀

【适用范围】供各类人员在非有创操作过程中佩带，为防止病毒、细菌等病原体微生物、颗粒物等的直接透过提供一定的物理屏障。

【出口】可出口，美国FDA认证，欧盟CE认证：EN149

Is there any way to fully confirm or deny that these are counterfeit? I appreciate you response. Thanks!


**Jeff S. Sandy, CAMS, CFE**
***Cabinet Secretary***
**Department of Military Affairs and Public Safety**
**State Capitol Complex Room W-400**
**1900 Kanawha Boulevard East**
**Charleston, WV 25305**
304-558-2930 (office)
304-553-6826 (cell)

## Sandy, Jeff

**From:** Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>
**Sent:** Wednesday, April 15, 2020 12:51 PM
**To:** Sandy, Jeff
**Subject:** RE: As discussed

Good afternoon, Mr. Sandy,

I believe this is the link you are looking for:

https://www.fda.gov/media/136664/download

Please let me know if this is not correct and I can look again.

Regards,

- Mayo

**Mayo Shirley**
*Executive Assistant*
**Office of the Commissioner**
**Office of the Chief Scientist**
**U.S. Food and Drug Administration**
Tel: 301 796-4616
mayo.shirley@fda.hhs.gov




**From:** Sandy, Jeff <Jeff.Sandy@wv.gov>
**Sent:** Wednesday, April 15, 2020 12:44 PM
**To:** Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>
**Subject:** As discussed

**Jeff S. Sandy, CAMS, CFE**
***Cabinet Secretary***
**Department of Military Affairs and Public Safety**
**State Capitol Complex Room W-400**
**1900 Kanawha Boulevard East**
**Charleston, WV 25305**
304-558-2930 (office)
304-553-6826 (cell)

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

3. There is no adequate, approved, and available alternative to the emergency use of the authorized respirators for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.[3,4]

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized respirators listed in Appendix A, and includes authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system,[5] for use in healthcare settings by HCP as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

### Respirators Eligible for Authorization under this EUA

A disposable non-NIOSH-approved respirator manufactured in China that meets one of the following criteria for authentication is eligible for authorization under this EUA:

1. It is manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA;
2. It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA; or
3. It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA.[6]

A respirator that meets the eligibility criteria outlined above will be added to Appendix A as an authorized respirator once FDA confirms the criteria for issuance are met. FDA may ask a manufacturer that is requesting authorization for any additional information FDA needs to confirm the respirator is eligible under one of the criteria outlined above. Once FDA receives the requisite information, FDA will notify the manufacturer of the inclusion of its authorized respirator(s) in Appendix A under this EUA by replying to the manufacturer's or importer's email. This process is further outlined below.

---

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[4] There are not sufficient quantities of FFRs that are both NIOSH-approved and meet FDA regulatory requirements to meet the needs of the U.S. healthcare system. These disposable respirators are an integral part of routine patient care. Providing HCP who are on the forefront of the COVID-19 response with FFRs consistent with the CDC's guidance and recommendations is necessary in order to reduce the risk of illness in HCPs and increase their willingness to provide care to affected patients or those suspected of having COVID-19.

[5] For purposes of this EUA, an "authorized decontamination system" means any decontamination system that has been issued an EUA. Authorized decontamination systems can be found on FDA's Emergency Use Authorization webpage, available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[6] Manufacturers of respirators designed and validated according to China's standards are eligible for authorization if this criterion is met.

**Authorized Respirators**

In order to be added to Appendix A as an authorized respirator under this EUA, manufacturers and/or importers must demonstrate that the disposable non-NIOSH-approved respirator(s) manufactured in China meets at least one of the criteria above by sending a request to FDA with the subject line "FFRS Made in China" to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the information below:

A. For respirators meeting criterion #1 above, please provide:

- The manufacturer name, model number and NIOSH approval numbers for your NIOSH approved respirator(s)
- The manufacturer name, address, model number, and a copy of the product labeling[7] for the respirator you want authorized
- An estimate of the number of respirators you are planning to import during the public health emergency

B. For respirators meeting criterion #2 above, please provide:

- The manufacturer name, address, model number, and a copy of the product labeling[8] for the respirator you want authorized
- Marketing authorization document/certificate from another regulatory authority or conformity assessment body acting on their behalf (including the authorization number and the name of the conformity assessment body)
- Certificate of conformity to the applicable standards
- An estimate of the number of respirators you are planning to import during the public health emergency

C. For respirators meeting criterion #3 above, please provide:

- The manufacturer name, address, model number, and a copy of the product labeling[9] for the respirator you want authorized
- Name of the testing body
- Certificate of conformity to the applicable standards
- Test report demonstrating applicable performance standards have been met
- An estimate of the number of respirators you are planning to import during the public health emergency

The above-described authorized respirators listed in Appendix A, when labeled as described in this letter, are authorized to be distributed to and used in healthcare settings by HCPs when used

[7] Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.
[8] Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.
[9] Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

in accordance with CDC's recommendations under this EUA, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

Additionally, authorized respirators listed in Appendix A that have been decontaminated using an authorized decontamination system remain authorized under this EUA to be used in healthcare settings by HCP when used in accordance with the terms and conditions of the authorized decontamination system without the need for any action by the respirators' manufacturer, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized respirators when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence and other information available to FDA, that it is reasonable to believe that the authorized respirators may be effective at preventing HCP exposure to certain particulates to prevent disease spread, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific and other information available to FDA, including the information supporting the conclusions described in Section I above, and conclude that the authorized respirators, when used in healthcare settings to prevent HCP exposure to certain particulates to prevent disease spread (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized respirators are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA. EUA amendments may be undertaken as needed with concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

## III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality

system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized respirators that are used in accordance with this EUA.

## IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

### Manufacturers of Authorized Respirators

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

C. Manufacturers of authorized respirators will notify the importer (if applicable) of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

D. Manufacturers of authorized respirators will have a process in place for reporting adverse events of which they become aware and send such reports to FDA.

E. All descriptive printed material relating to the use of the authorized respirators in the United States shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

F. No descriptive printed matter relating to the use of the authorized respirators in the United States may represent or suggest that the product is safe or effective for the prevention of COVID-19.

G. Manufacturers of authorized respirators will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made

available to FDA for inspection upon request.

H. Manufacturers of authorized respirators that are decontaminated by an authorized decontamination system are not responsible for any additional conditions that may apply to the manufacturer and/or operator of the decontamination system, unless they are the same manufacturer.

**Importers**

I. All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

J. No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.

K. Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

L. Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.

**Manufacturers and/or Operators of Authorized Decontamination Systems**

M. Each manufacturer and/or operator of an authorized decontamination system for decontamination of authorized respirators must comply with the Conditions of Authorization and authorized labeling as set forth in the Letter of Authorization for the authorized decontamination system.

The emergency use of the authorized respirators as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

## V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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

3. There is no adequate, approved, and available alternative to the emergency use of the authorized respirators for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.[3,4]

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized respirators listed in Appendix A, and includes authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system,[5] for use in healthcare settings by HCP as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

### Respirators Eligible for Authorization under this EUA

A disposable non-NIOSH-approved respirator manufactured in China that meets one of the following criteria for authentication is eligible for authorization under this EUA:

1. It is manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA;
2. It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA; or
3. It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA.[6]

A respirator that meets the eligibility criteria outlined above will be added to Appendix A as an authorized respirator once FDA confirms the criteria for issuance are met. FDA may ask a manufacturer that is requesting authorization for any additional information FDA needs to confirm the respirator is eligible under one of the criteria outlined above. Once FDA receives the requisite information, FDA will notify the manufacturer of the inclusion of its authorized respirator(s) in Appendix A under this EUA by replying to the manufacturer's or importer's email. This process is further outlined below.

---

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[4] There are not sufficient quantities of FFRs that are both NIOSH-approved and meet FDA regulatory requirements to meet the needs of the U.S. healthcare system. These disposable respirators are an integral part of routine patient care. Providing HCP who are on the forefront of the COVID-19 response with FFRs consistent with the CDC's guidance and recommendations is necessary in order to reduce the risk of illness in HCPs and increase their willingness to provide care to affected patients or those suspected of having COVID-19.

[5] For purposes of this EUA, an "authorized decontamination system" means any decontamination system that has been issued an EUA. Authorized decontamination systems can be found on FDA's Emergency Use Authorization webpage, available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[6] Manufacturers of respirators designed and validated according to China's standards are eligible for authorization if this criterion is met.

**Authorized Respirators**

In order to be added to Appendix A as an authorized respirator under this EUA, manufacturers and/or importers must demonstrate that the disposable non-NIOSH-approved respirator(s) manufactured in China meets at least one of the criteria above by sending a request to FDA with the subject line "FFRS Made in China" to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the information below:

A. For respirators meeting criterion #1 above, please provide:

- The manufacturer name, model number and NIOSH approval numbers for your NIOSH approved respirator(s)
- The manufacturer name, address, model number, and a copy of the product labeling[7] for the respirator you want authorized
- An estimate of the number of respirators you are planning to import during the public health emergency

B. For respirators meeting criterion #2 above, please provide:

- The manufacturer name, address, model number, and a copy of the product labeling[8] for the respirator you want authorized
- Marketing authorization document/certificate from another regulatory authority or conformity assessment body acting on their behalf (including the authorization number and the name of the conformity assessment body)
- Certificate of conformity to the applicable standards
- An estimate of the number of respirators you are planning to import during the public health emergency

C. For respirators meeting criterion #3 above, please provide:

- The manufacturer name, address, model number, and a copy of the product labeling[9] for the respirator you want authorized
- Name of the testing body
- Certificate of conformity to the applicable standards
- Test report demonstrating applicable performance standards have been met
- An estimate of the number of respirators you are planning to import during the public health emergency

The above-described authorized respirators listed in Appendix A, when labeled as described in this letter, are authorized to be distributed to and used in healthcare settings by HCPs when used

[7] Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.
[8] Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.
[9] Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

in accordance with CDC's recommendations under this EUA, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

Additionally, authorized respirators listed in Appendix A that have been decontaminated using an authorized decontamination system remain authorized under this EUA to be used in healthcare settings by HCP when used in accordance with the terms and conditions of the authorized decontamination system without the need for any action by the respirators' manufacturer, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized respirators when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence and other information available to FDA, that it is reasonable to believe that the authorized respirators may be effective at preventing HCP exposure to certain particulates to prevent disease spread, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific and other information available to FDA, including the information supporting the conclusions described in Section I above, and conclude that the authorized respirators, when used in healthcare settings to prevent HCP exposure to certain particulates to prevent disease spread (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized respirators are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA. EUA amendments may be undertaken as needed with concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

## III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality

system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized respirators that are used in accordance with this EUA.

## IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

### Manufacturers of Authorized Respirators

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

C. Manufacturers of authorized respirators will notify the importer (if applicable) of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

D. Manufacturers of authorized respirators will have a process in place for reporting adverse events of which they become aware and send such reports to FDA.

E. All descriptive printed material relating to the use of the authorized respirators in the United States shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

F. No descriptive printed matter relating to the use of the authorized respirators in the United States may represent or suggest that the product is safe or effective for the prevention of COVID-19.

G. Manufacturers of authorized respirators will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made

available to FDA for inspection upon request.

H. Manufacturers of authorized respirators that are decontaminated by an authorized decontamination system are not responsible for any additional conditions that may apply to the manufacturer and/or operator of the decontamination system, unless they are the same manufacturer.

**Importers**

I. All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

J. No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.

K. Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

L. Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.

**Manufacturers and/or Operators of Authorized Decontamination Systems**

M. Each manufacturer and/or operator of an authorized decontamination system for decontamination of authorized respirators must comply with the Conditions of Authorization and authorized labeling as set forth in the Letter of Authorization for the authorized decontamination system.

The emergency use of the authorized respirators as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

## V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

**Appendix A: Authorized Respirators**
*Updated: April 10, 2020*

**The Authorized Respirators**

Authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

**Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China**

| Manufacturer | Respirator Model(s) | Country of Manufacture |
|---|---|---|
| 3M | 9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V | China |
| Allmed | KN95 Particulate Respirator LP220002 | China |
| Bei Bei Safety Co Ltd. | B702, B702V, B704, B704V | China |
| BYD Precision Manufacture Co. Ltd. | BYD KN95 Particulate Respirator (Model Number: DG3101) | China |
| Chengde Technology Co. | KN95 (PM 2.5) Protective Mask | China |
| CTT CO. Ltd. | KN95 | China |
| Fujian Kang Chen Daily Necessities Co, Ltd. | K0450, 57793 | China |
| Fujian Yongtai Sanlian Garment Co., Ltd. | N95 | China |
| Guangzhou Aiyinmei Co., LTD | A&F KN95 | China |
| Guangzhou Harley Commodity Company Limited | L-130V KN95 | China |
| Guangzhou Improve Medical Instruments Co., LTD | PPDS N95 Respirator and Surgical Mask Model No. PPDS Ear Hook M | China |

| | | |
|---|---|---|
| Guangzhou Powecom Labor Insurance Supplies Co., LTD | KN95 | China |
| Guangdong ZhiZhen Biological Medicine Co., LTD | KN95 | China |
| Huizhou Jiahe Cubic Technology Co., LTD | KN95 | China |
| Improve Medical (Hunan) Co. Ltd. | PPDS Strap Headband M<br>PPDS Ear Hook M | China |
| Jiangsu Weichuangli New Materials Co., Ltd. | WCL-0075 | China |
| Jinan Vhold Co., LTD | VH-95 | China |
| Juntech (Jiaxing) Healthcare Materials Co. Ltd | KN95 | China |
| Panzhihua Gangcheng Group Yasheng Industrial Co., Ltd. | KN95 | China |
| Qingyuan Leite Technology Development Co. | GV-0095A, GVHKN95 | China |
| Raxwell Industrial Technology (Shanghai) Co., Ltd. | RX9501 | China |
| Shandong Daddy's Choice Health Science and Technology Co., Ltd | Purism KN95 | China |
| Shandong Shengquan New Material Co., Ltd | SNN70370B (Willow leaf form valveless) | China |

| | | |
|---|---|---|
| Shanghai Dasheng Health Products Manufacture Company, Ltd. | DTC3X-1, DTC3X-2, DTC3X-3, DTC3B-1 | China |
| Shauguan Taijie Protection Technology Co. Ltd. | KN95 | China |
| Shenzhen Missadola Technology Co., Ltd, dba 1AK Medical Supplies | 2626-1 KN95 | China |
| Tianjin Benmo Medical Equipment Co., Ltd. | KN95 | China |
| Weini Technology Development Co., Ltd | FFP2 NR E-300, FFP2 NR E-680, FFP2 NR 952, FFP2 NR F-820, KN95 958, KN95 951 | China |
| Yiwu Yifan Knitting Co. Ltd | KN95 | China |
| Zhejiang Shengtai Baby Products Co Ltd | KN95 | China |
| Zhengzhou Ripe Medical Technology Co., LTD | Disposable Protective Mask KN95 | China |
| ZhongKang protective equipment technology (Guangzhou) Co., Ltd | ZK601 | China |