UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Case No. 20-MJ-15272
v.	:	
CRAWFORD TECHNOLOGY (HK) CO., LTD.	:	**CRIMINAL COMPLAINT**

I, the undersigned complainant, being duly sworn, state the following is true and correct to the best of my knowledge and belief.

SEE ATTACHMENT A

I further state that this Complaint is based on the following facts:

SEE ATTACHMENT B

☑ continued on the attached pages and made a part hereof.

Special Agent Joseph Jerla
U.S. Food & Drug Administration

Agent Joseph Jerla attested to this Complaint by telephone in accordance with the requirements of Fed. R. Crim. P. 4.1 on June 17, 2020.

Hon. Edward S. Kiel

HON. EDWARD S. KIEL
United States Magistrate Judge

4:08pm

ATTACHMENT A

COUNT ONE

(Introduction of Misbranded Devices into Interstate Commerce)

On or about May 6, 2020, in the District of New Jersey, and elsewhere, the Defendant,

CRAWFORD TECHNOLOGY (HK) CO., LTD.

did introduce and deliver for introduction, and cause to be introduced and delivered for introduction into interstate commerce, devices that were misbranded within the meaning of Title 21, United States Code, Section 352(a)(1), specifically, KN95 respirators, whose labeling falsely claimed that they were 95% efficient in filtering hazardous particulates and were compliant with the regulatory standards for such respirators in the European Union and elsewhere.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1), and Title 18, United States Code, Section 2.

ATTACHMENT B

I, Joseph Jerla, am a Special Agent with the United States Food and Drug Administration ("FDA"). I am fully familiar with the facts set forth herein based on my own investigation, my conversations with other law enforcement officers, and my review of reports, documents, and items of evidence. Because this Complaint is being submitted for the limited purpose of establishing probable cause, I have not set forth each and every fact that I know concerning this investigation. I have set forth only the facts that I believe are necessary to establish probable cause. Unless specifically indicated, all dates and times referenced herein are approximate, and all conversations, statements, and documents described are related in substance and in part.

1. At all times relevant to this Complaint:

a. Company-1 was a distributer of consumer electronic goods, including mobile phones, computers, headphones, tablets, gaming systems, and cameras. Company-1 maintained offices and a distribution center in New Jersey.

b. Defendant CRAWFORD TECHNOLOGY GROUP (HK) CO., LTD. ("Crawford") was a digital electronics company located in Shenzhen, China. Crawford was in the business of manufacturing accessories for mobile devices, including cases, screen protectors, cables, chargers, mounting brackets, headsets, wireless speakers, and other accessories.

2. As set forth in more detail below, in or around May 2020, during the global COVID-19 pandemic, Crawford sent approximately 140,400 adulterated and misbranded "KN95" filtering facepiece respirators to Company-1 for import into the United States (the "Crawford Respirators"). The packaging for the Crawford Respirators, as well as the Crawford Respirators themselves, falsely indicated that they were 95% efficient at filtering harmful airborne particles. The Crawford Respirators and their packaging also claimed that they complied with established standards in the European Union and China for such respirators, which require at least 94% or 95% filtering efficiency, respectively. These claims were false and misleading because the average filtering efficiency for the Crawford Respirators was far below the required thresholds: only approximately 22.33%. Accordingly, there is probable cause to believe that Crawford violated the federal Food, Drug, and Cosmetic Act, specifically, Title 21, United States Code, Sections 331(a) and 333(a)(1).

The Global COVID-19 Pandemic and Respirator Shortages

3. In December 2019, a novel coronavirus, SARS-CoV-2, was first detected in Wuhan Province, China, causing outbreaks of the coronavirus disease 2019 ("COVID- 19") that have since spread globally. On January 31, 2020, the Secretary of Health and Human Services declared a national public health emergency under 42 U.S.C. § 247d as a result of the spread of COVID-19 to and within the United States. On March 11, 2020, the Director-General of the World Health Organization characterized COVID-19 as a pandemic. On March 13, 2020, the President of the United States issued Proclamation 9994 declaring a national emergency as a result of the rapid spread of COVID-19 within the United States.

4. According to the CDC, the virus that causes COVID-19 spreads through respiratory droplets produced when an infected person coughs or sneezes. Droplets can land in the mouths, noses, or eyes of people who are nearby or possibly be inhaled into the lungs of those within close proximity.

5. Accordingly, the CDC has issued guidance to health care providers recommending that they wear personal protective equipment ("PPE"), such as N95 or similar respirators, to prevent the coronavirus from being transmitted by infected patients to healthcare providers. The CDC also has encouraged the public to use face coverings to prevent the spread of the virus. To that end, on or about April 8 and April 11, 2020, New Jersey Governor Phil Murphy issued two executive orders requiring, among other things, that people working in or patronizing essential businesses and services like grocery stores and public transportation wear face coverings.

6. According to CDC guidance, face masks are used by the general public and by healthcare professionals as source control, which refers to the use of a face mask or cloth face covering over the mouth and nose to contain an individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.[1] Face masks sometimes contain ear loops, which are not designed to form a seal around the nose and mouth.

7. An N95 respirator is a disposable half-mask filtering facepiece respirator that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level pursuant to 42 CFR § 84.170, which requires that the respirator have a minimum efficiency level of 95% (*i.e.*, 95% of particulates/aerosols are filtered by the respirator). In the United States, the National Institute for Occupational Safety and Health ("NIOSH") of the CDC tests respirators and other products to ensure that they meet certain safety standards. A NIOSH-approved N95 respirator is an N95

[1] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

respirator approved by NIOSH that meets the filtration efficiency level set forth in 42 CFR 84.171. Certain N95 respirators that are approved by NIOSH may be exempt from FDA premarket notification requirements.

8. Similar standards exist outside the United States. For example, in the European Union, respirators designated "FFP2" must meet the EN 149:2001 standard, which requires that the respirator be at least 94% efficient at blocking hazardous particulates. China's standard for measuring the efficiency of half-face respirators designated "KN95" is GB2626-2006, which requires that the respirator have at least 95% filtering efficiency.

9. The CDC does not recommend that the general public wear N95 respirators to protect themselves from respiratory diseases, including COVID-19, as those are critical supplies that must be reserved for health care workers and other medical first responders.

10. Due to the unprecedented demand for emergency medical services to treat patients presenting with COVID-19 symptoms, hospitals and medical professionals have experienced critical shortages of N95 or similar respirators. Accordingly, on March 24, 2020, in response to the evolving COVID-19 public health emergency and continued shortage of filtering facepiece respirators, the FDA issued an Emergency Use Authorization ("EUA") to allow the use of filtering facepiece respirators from specific countries that evaluate the safety of such devices using methods similar to NIOSH. These countries and regions include Australia, Brazil, Europe, Japan, Korea, and Mexico. The FDA issued an update to the EUA on April 3, 2020 to include certain respirators manufactured in China. The Crawford Respirators were not authorized under the EUA. Due, in part, to concerns regarding ineffective, misbranded, and mislabeled respirators manufactured in other countries being shipped to the United States, the FDA issued several amended EUAs, most recently on June 6, 2020.[2]

Statutory Framework of the Food, Drug, and Cosmetic Act

11. The FDA is responsible for protecting the health of the American public by ensuring, among other things, that medical devices are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA, among other things, regulates the manufacture, labeling, and distribution of medical devices shipped or received in interstate commerce and enforces the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "FDCA"), and other pertinent laws and regulations.

[2] The FDA's current EUA governing Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators is available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe.

12. The FDCA prohibits, among other things, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded device. 21 U.S.C. § 331(a). A violation of the statute committed with an intent to defraud or mislead converts the offense from a strict liability misdemeanor to a felony. 21 U.S.C. § 333(a)(2). This case is brought under the statute's strict liability misdemeanor provision. 21 U.S.C. § 333(a)(1).

13. Under the FDCA, a medical device is misbranded if, among other things, the labeling on the device "is false or misleading in any particular." 21 U.S.C. § 352(a)(1).

14. Under the FDCA, a "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). "Labeling" is defined as "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." 21 U.S.C. § 321(m).

15. Under the FDCA, "interstate commerce" is defined, in part, as "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b).

16. Under the FDCA, a "device" is defined, in pertinent part, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . , and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

17. Face masks, face shields, and respirators are "devices" subject to FDA regulation when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face masks, face shields, and respirators are not devices when they are intended for a non-medical purpose, such as for use in construction.

18. Under the FDCA, every person who owns or operates any establishment within any foreign country engaged in the manufacture of a device that is imported or offered for import into the United States shall, upon first engaging in such activity, immediately submit a registration to the FDA that includes, among other things, the name and place of business of the establishment, the name of the United States agent for the establishment, and the name of each importer of such device in the United States that is known to the establishment. 21 U.S.C. § 360(i)(1)(ii).

19. Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device imported into the United States must identify a United States agent as part of their FDA registration process. The responsibilities of the United States agent include: assisting the FDA in communications with the foreign establishment; responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States; and assisting the FDA in scheduling inspections of the foreign establishment. 21 CFR § 807.40(b)(2). If the FDA is unable to contact the foreign establishment directly or expeditiously, the FDA may provide information or documents to the U.S. agent, and such an action shall be considered equivalent to providing the same information or documents to the foreign establishment. *Id.* In addition, the United States agent cannot be a mailbox, answering machine or service, or any other place where an individual acting as the foreign establishment's agent is not physically present. 21 CFR § 807.3.

Crawford's Registration with the FDA

20. On or about May 1, 2020, Crawford completed the registration process with the FDA as a foreign exporter and manufacturer of medical devices. As part of its registration process, Crawford listed five separate classifications of medical devices, as set forth below.

- Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per IIE Guidance - Face Mask, Disposable Face Mask, Surgical Mask, Disposable Face Mask
- Sunglasses (Non-Prescription Including Photosensitive) - Eye Protector
- Non-Surgical Isolation Gown - Protective Clothing
- Radiographic Protective Glove - Disposable Gloves
- Accessory, Surgical Apparel - Accessory

21. As required as part of its registration with the FDA, Crawford initially listed its U.S. Agent as CCTC Service, Inc. ("CCTC"), located at an address in Wilmington, Delaware. The investigation revealed that the address listed in Crawford's FDA registration for CCTC is a personal residence with no affiliation to CCTC. Law enforcement interviewed the occupant of the residence, who stated that he was a clinical psychologist who has rented the premises for three years.

22. On or about May 28, 2020, law enforcement attempted to reach out multiple times to the phone number listed by Crawford in its registration documents. Each time, law enforcement received a message stating that the number was temporarily unavailable. Subsequent attempts to reach someone at that number were unsuccessful. CCTC did not respond to emails sent by

law enforcement to the email address listed for the company by Crawford on its initial registration documents. On or about June 12, 2020, the Agent listed in Crawford's FDA registration was changed to CCTC Services United Inc. at an address in Colorado.

23. On or about April 16, 2020, Company-1 communicated with a company located in Hong Kong ("Company-2") regarding purchasing KN95 respirators. As part of their communications, Company-2 sent Company-1 a document titled "Certification of FDA Registration" (the "Certification"). The Certification states: "This certifies that Crawford Technology (HK) Co. Limited . . . has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through Shenzhen CTT Testing Technology Co., Ltd." The Certification has a logo of a bald eagle wrapped in an American flag banner as well as the official FDA logo. The Certification lists Crawford's assigned Owner/Operator number and features the word "Crawford" as a repeated watermark in the background of the document. The Certification lists five different device codes, including face masks, eye protection, non-surgical isolation gowns, protective gloves, and surgical apparel accessories.

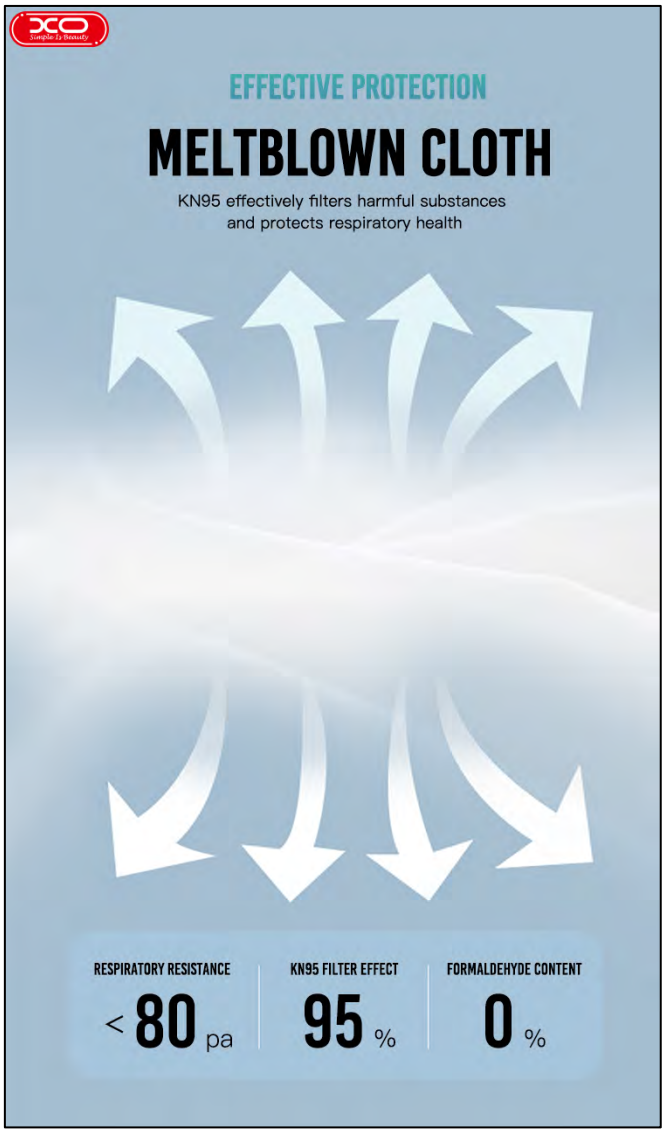
Crawford's Importation of Respirators with False and Misleading Labeling

24. As indicated above, Crawford is a digital electronics company located in Shenzhen, China that is in the business of manufacturing accessories for mobile devices including cases, screen protectors, cables, chargers, mounting brackets, headsets, wireless speakers, and other accessories.

25. To promote and sell its goods, Crawford maintains a web page available in both Chinese and English. The English version of Crawford's web page contains a home page with seven main tabs, each prominently displayed at the top of the page. The tabs include "Phone case," "Glass" (which features tempered glass screen protectors for mobile phones), "Creative" (various phone accessories), "USB Cable," "Headset," "Network" (a list of Crawford's stores and marketing centers in China), and "epidemic." The "epidemic" tab links to a separate page with various products including protective eyeware, hand sanitizer, infrared thermometers, disposable surgical-type masks, and KN95 respirators. One of the KN95 products featured on Crawford's "epidemic" web page is a respirator called "KN95 Stereo Protection" (defined above and referred to herein as the "Crawford Respirators").

26. The page featuring the Crawford Respirators states that the respirators have "4 layers of protection" and "Passed the national standard 2626-2000 test." The page also says "KN95 Filtration reaches 95%," "KN95 Filter Effect 95%," and states that the Crawford Respirators protect against "Severe Haze," Bacteria," and "Dust." The page for the Crawford Respirators

also contains photographs of a "Certification Report," but the report is not available for review or download. Several images from Crawford's web page featuring the Crawford Respirators are shown below.



27. Beginning in or around March through at least May 2020, Company-1 attempted to purchase, and did purchase, large quantities of PPE, including filtering facepiece respirators, from manufacturers in China and elsewhere. Company-1 advertised the PPE for sale to third parties to use to prevent the spread and transmission of COVID-19. On or about April 6, 2020, a Crawford employee (the "Crawford Employee") sent an employee of Company-1 information regarding the Crawford Respirators. The information provided by the Crawford Employee was substantially similar to that found on Crawford's website, including photographs of the Crawford Respirators as well as representations about the respirators' performance standards, including that they "Passed the national standard 2626-2000 test," "KN95 Filtration reaches 95%," "KN95 Filter Effect 95%," and that the respirators protect against "Severe Haze," Bacteria," and "Dust."

28. The Crawford Employee also sent Company-1's employee a document titled "Test Report," purportedly issued on March 31, 2020, for disposable KN95 respirators sold by Crawford with model numbers XO-01, XO-02, XO-03, and XO-04 (the "Test Report"). The Test Report stated that it was prepared by a company located in Shenzhen, China. According to the Test Report, the Crawford Respirators were tested pursuant to EN 149:2001+A1:2009, a European standard for measuring the efficiency of half-face respiratory masks. The Test Report concluded that the Crawford Respirators were in "full compliance" with the EN 149:2001+A1:2009 standard, specifically a sub-category under that standard referred to as FFP2, indicating a minimum filtration efficiency of 94%.

29. Thereafter, in or around April 2020, Company-1 purchased at least 140,400 Crawford Respirators from Crawford for approximately $1.07 each, totaling approximately $150,228. Purchase orders issued by Company-1 to Crawford list the address of Company-1's distribution center in New Jersey as the address to which the Crawford Respirators should be shipped. The investigation has revealed that Crawford first shipped the Crawford Respirators to Hong Kong, where they were then shipped to the United States.

30. On or about May 6, 2020, a shipment containing Crawford Respirators addressed to Company-1's distribution center in New Jersey arrived at John F. Kennedy International Airport in New York from Hong Kong. The packing list included with the shipment indicated that it was prepared by Crawford and that the shipment contained approximately 140,700 Crawford Respirators.

31. Upon arrival, U.S. Customs and Border Protection ("CBP") held the Crawford Respirators for further inspection. As seen in the images below, labels on the boxes indicate that the Crawford Respirators were manufactured on April 14, 2020 by "shenzhen Crawford Technology Co., Ltd." and the "executive company" is listed as Crawford. The outside of the boxes in which the Crawford Respirators were packaged also says, in multiple places, "KN95 Face Mask," "High-Concentration anion and antibacterial," and "Executive standard: GB2626-2006 & EN 149:2001 + A1:2009."

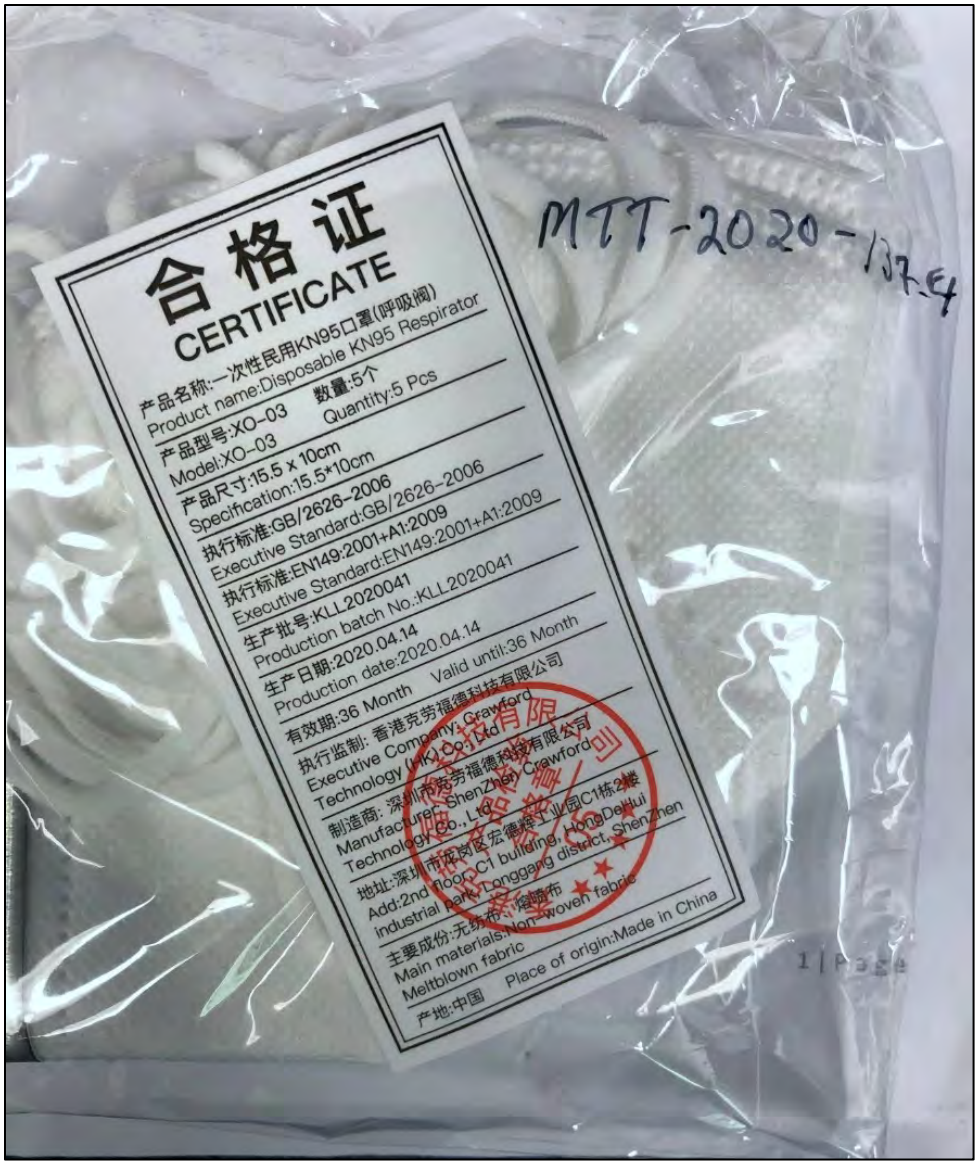
32. The interior packaging of the Crawford Respirators contained a "Certificate," which indicates that they comport with the Chinese standard GB 2626-2006 and European standard EN 149:2001 + A1:2009.

33. One side of each Crawford Respirator is imprinted with the Crawford corporate logo as well as "CE FFP2" and "EN 149:2001 + A1:2009." The other side of the respirator is imprinted with "KN95" and "GB2626-2006."


MTT-2020-137.4
XO
Simple Is Beauty
KN95 FACE MASK
High-Concentration anion and antibacterial
Foldable Design
Comfortable and breathable
4 Layers Standard version
CARE WITH HEART
CE
10 PCS


XO
Simple Is Beauty
KN95 FACE MASK
High-Concentration anion and antibacterial
1
2
3
4
5
1. Open the mask smoothly
2. Face to face of the mask without a nose clip so that the nose clip is above the mask
3. Pull the belt behind the ear
4. The middle part of the nose clip, press inward from the middle to both sides according to the strip shape of the nose beam until it is completely pressed into the shape of the nose beam, only one hand pinch of the mask pen clip may affect the tightness of the mask
5.Before entering the work area ,must check the tightness of the mask and face
Model:XO-01
Executive Company: Crawford Technology (HK)Co.,ltd
Manufacturer:shenzhen Crawford Technology Co ., LTD
Executive Standard:GB2626-2006
EN149:2001+A1:2009
Production date:2020.04.14
Valid until:2023.04.14
ATTENTIONS :
1. Wash your hands according to the rules before wearing the mask, and avoid touching the inside of the mask when wearing it.
2. The mask must be replaced in time if it is dirty, deformed, damaged, or has an unusual smell.
3. The masks should be stored separately to avoid contact with each other and identify the users of the masks.
4. masks can not be disinfected with disinfectants, heating and other methods
CRAWFORD TECHNOLOGY (HK) CO.,LTD
WARNING
The picture is only for reference,please make the object as the standard.
+86(0755)83512732
www.hkcrawford.com
PRINTED WITH SOYINK
XO hkcrawford
XO hkcrawford


CE FFP2
EN149:2001+A1:2009
XO
KN95
GB2626-2006



34. On or about May 13 or 14, 2020, CBP sent samples of the Crawford Respirators to the NIOSH for testing.[3]

35. As part of its testing process, NIOSH tested 19 different Crawford Respirators for their filtration efficiency (*i.e.*, the percentage of

[3] As part of its national response to the Covid-19 epidemic, NIOSH's National Personal Protective Technology Laboratory ("NPPTL") began conducting tests of respirators manufactured in other countries that purported to comply with standards promulgated by other countries, including China and the European Union. "These assessments were developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers and other workers due to the respirator shortage associated with COVID-19." NPPTL Respirator Assessments to Support the COVID-19

particulates/aerosols filtered by the respirator). The results showed that the Crawford Respirators ranged in efficiency from 14.60% to 44.2%. The average efficiency across all 19 Crawford Respirators tested was 22.33%. This is far below the 94% efficiency benchmark required to comply with the European FFP2 (EN 149:2001 + A1:2009) standard FPP2 respirators or the 95% benchmark required to comply with Chinese standard KN95 respirator designation (GB2626-2006) that is displayed on the packaging of the Crawford Respirators, and as advertised by Crawford's website. Accordingly, there is probable cause to believe that the Crawford Respirators and their packaging contain false and misleading claims about their effectiveness and, therefore, are misbranded pursuant to the Food, Drug, and Cosmetic Act.

Response (June 10, 2020), *available at* https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html. The results of the tests are publicly available at the web address above. Specifically, the results of the Crawford Respirators are available at https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-137.4_International_ShenzhenCrawford_XO-01-or-XO-03_TestReport_Redacted-508.pdf.