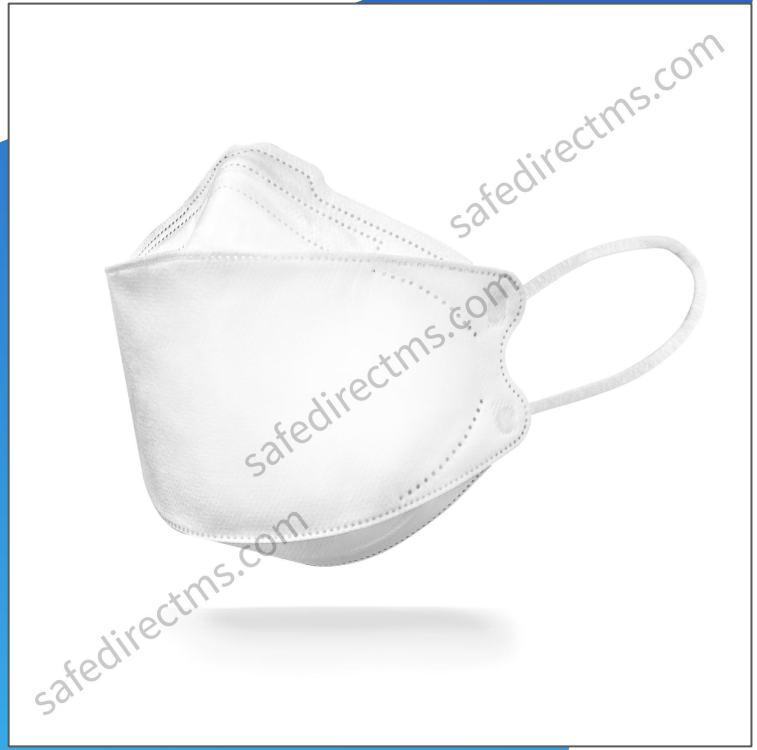
SAFE DIRECT
MEDICAL SUPPLIES

A proudly Canadian company

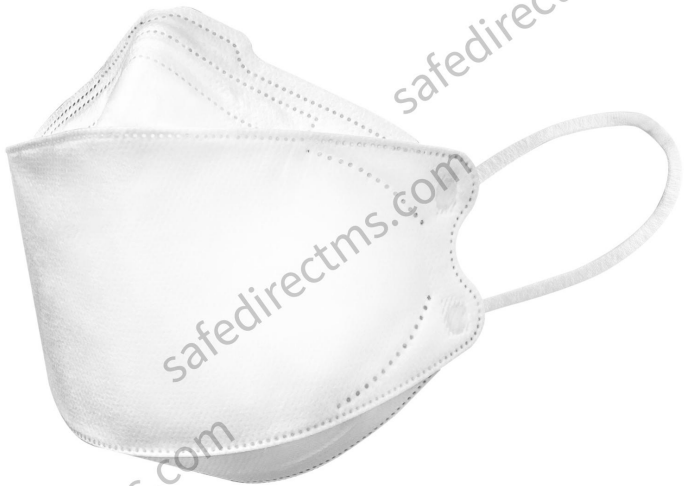
# KN95 Protective Mask

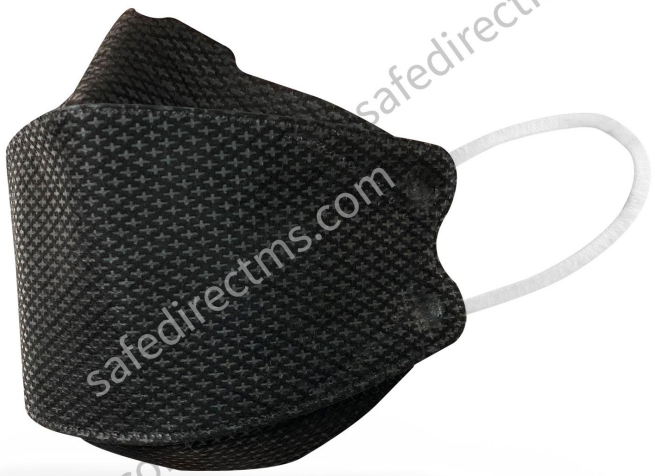
## Bacterial Filtration Efficiency ≥ 95%

*Redacted Version*



## White and black colour options available





## Medical Standard GB19083-2010 & Commercial Standard GB2626-2006 Available

**Table 2: KN95 specifications**

| | Medical KN95 (GB 19083-2010) | Commercial KN95 (GB2626-2006) |
|---|---|---|
| **Labelling Information on respirator** | • Number and year of publication of standard<br>• Type and grade of filter elements (i.e. KN95) | |
| **Nasal splints** | Must be adjustable | N/A |
| **Mask Harness** | • No less than 10 Newton (1kg) per strap<br>• Earloops Are Allowed | |
| **Fit** | The mask shall be designed as to provide a good fit and overall fit factor of the mask shall **not be less than 100** | The disposable facepiece structure shall ensure the tight fitting with face, and be free from deformation during the service life. |
| **Filter performance – (must be ≥ X% efficient)** | ≥ 95% | ≥ 95% |
| **Test agent** | Sodium Chloride (NaCl) Particles | Sodium Chloride (NaCl) Particles |

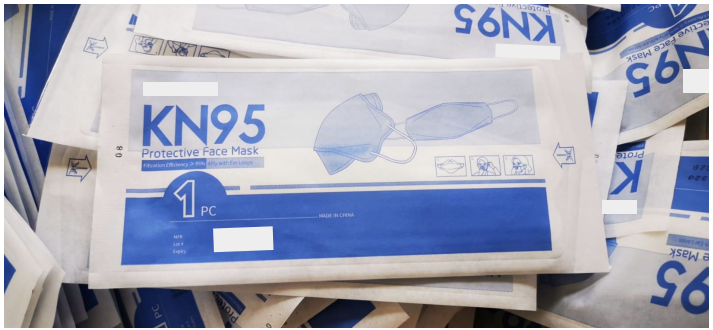
## Medical Packaging Option

### Full Case Count

- 200 units/ case
- Masks individually wrapped
- Black and white options available
- 85 cases/ pallet

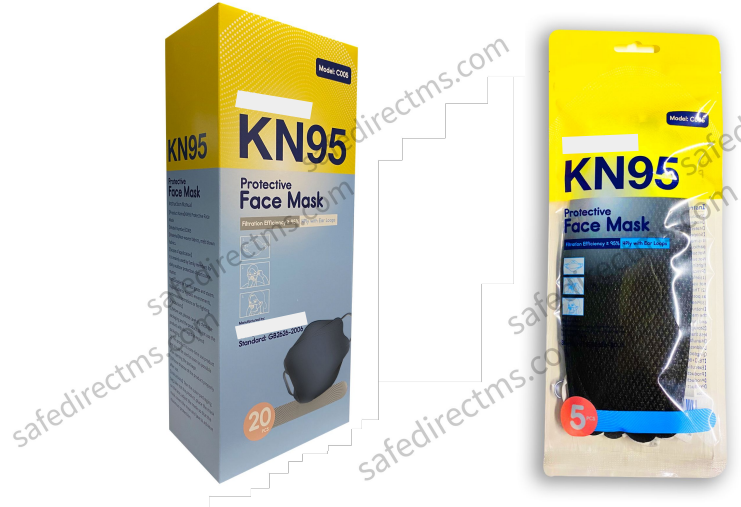
### Full Case Dimensions

- 11.5 x 10.5 x 10 inches




## Retail Packaging Option

- Case of 20 in a box
- Includes 4 packs of 5 masks
- Black and white options available



NELSON LABORATORIES

Sponsor:

## Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article: Respirator Face Mask
Study Number:
Study Received Date: 03 Feb 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0014 Rev 07

**Summary:** This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m$^3$. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

**Results:** The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

| Test Article Number | Initial Airflow Resistance (mm $H_2O$) | Particle Penetration (%) | Filtration Efficiency (%) |
|---|---|---|---|
| 1 | 6.9 | 1.02 | 98.98 |
| 2 | 6.8 | 1.23 | 98.77 |
| 3 | 6.8 | 1.24 | 98.76 |
| 4 | 7.0 | 1.08 | 98.92 |
| 5 | 6.6 | 1.12 | 98.88 |
| 6 | 7.3 | 1.12 | 98.88 |
| 7 | 7.1 | 1.03 | 98.97 |
| 8 | 6.6 | 1.13 | 98.87 |
| 9 | 7.4 | 1.06 | 98.94 |
| 10 | 6.9 | 1.17 | 98.83 |
| 11 | 6.8 | 1.18 | 98.82 |
| 12 | 7.1 | 1.25 | 98.75 |
| 13 | 7.5 | 1.14 | 98.86 |

Study Director Brandon L. Williams

Study Completion Date







| Test Article Number | Initial Airflow Resistance (mm $H_2O$) | Particle Penetration (%) | Filtration Efficiency (%) |
|---|---|---|---|
| 14 | 7.5 | 1.44 | 98.56 |
| 15 | 7.4 | 1.10 | 98.90 |
| 16 | 7.2 | 1.37 | 98.63 |
| 17 | 7.2 | 1.23 | 98.77 |
| 18 | 6.9 | 1.36 | 98.64 |
| 19 | 7.7 | 1.26 | 98.74 |
| 20 | 7.3 | 1.25 | 98.75 |

**Acceptance Criteria:** The filter tester must pass the "Tester Set Up" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

**Filter Test Procedure:** Prior to testing, respirators were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) and 38 ± 2.5°C for 25 ± 1 hrs.

The filter tester used in this procedure was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 µm and a geometric standard deviation not exceeding 1.86 µm,. The mass median diameter is approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 min. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 pounds psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The neutralized NaCl test aerosol was verified to be at 25 ± 5°C and 30 ± 10% RH by the acceptance of the manufacturer's reference material. The NaCl concentration of the test aerosol was determined in mg/m$^3$ by a gravimetric method prior to the load test assessment.

An entire respirator was mounted on a test fixture, placed into the test article holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted the filter. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 filters was recorded.

# KN95 Protective Mask

161019130764

国检检测 CHINA COMPONENTS TEST

## Test Report

（2020） WSZ FHL

Product Name Protective Mask against haze

Applicant

Manufacturer

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co.,Ltd

## Test Report

[2020] WSZ FHL Page 1 of 2

| | | | |
|---|---|---|---|
| Product name | Protective Mask against haze | Specification | Willow leaf L |
| | | Brand | |
| Applicant/Add /Tel | | | |
| Manufacturer/ Add/Tel | | | |
| Sample grade | KN95 | Sample number | |
| Sample quantity | 26 PCS | Receiving date of sample | 2020.02.28 |
| Test type | Entrusted inspection | Article number/Batch number/Style number | Batch number：200203 |
| Test date | 2020/02/28~2020/03/02 | Test site | Testing room |
| Sample state | Meet the requirements | | |
| Test standard(s) | GB 2626-2006《Respiratory protective equipment -Non-powered purifying particle respirator》 | | |
| Test items | Filter efficiency、Respiratory resistance | | |
| Test conclusion | The sample upon examination, the projects meet the requirements of the Q/0285HNS 039 standard , the specific test results see page 2. Issue date: 2020.3.25 | | |
| Note | The Applicant requires the items inspected to be determined in accordance with Q/0285HNS 039 《protective mask》. The sample information are provided by Applicant. This report is only responsible for samples received. | | |

Approver: Reviewer: Main surveyor: 杨芸

## Test Result

[2020] WSZ FHL Page 2 of 2

| Number | Test item | | Unit | Technical requirements | Test Result | | Single Item decision |
|---|---|---|---|---|---|---|---|
| 1 | Filter efficiency | | — | ≥95.0% | Untreated | 98.9% | Qualified |
| | | | | | | 98.8% | |
| | | | | | | 99.1% | |
| | | | | | | 99.0% | |
| | | | | | | 99.1% | |
| | | | | | | 99.2% | |
| | | | | | | 98.7% | |
| | | | | | | 98.9% | |
| | | | | | | 98.9% | |
| | | | | | | 99.2% | |
| | | | | | Pretreatment | 99.0% | |
| | | | | | | 98.7% | |
| | | | | | | 98.8% | |
| | | | | | | 99.1% | |
| | | | | | | 99.3% | |
| 2 | Respiratory resistance | Inspiratory resistance | Pa | ≤175 | Untreated | 103.2 | Qualified |
| | | | | | | 98.7 | |
| | | | | | Pretreatment | 99.6 | |
| | | | | | | 97.3 | |
| | | Expiratory resistance | Pa | ≤145 | Untreated | 83.1 | Qualified |
| | | | | | | 80.2 | |
| | | | | | Pretreatment | 81.2 | |
| | | | | | | 80.7 | |
| Note | | | | | | | |

The End

# KN95 Protective Mask

CERTIFICATE

PAGE 1 of 2

## CERTIFICATE OF FDA REGISTRATION

Certification No.:

Dear Official Correspondent:
This document provides notification of the registration number assigned to your establishment:

Establishment:
Address:

Owner/Operator Number:
Registration Number:

General Manager
CTC REGISTRATION LLC
Email: ctc-086@hotmail.com
Web: http://www.ctc-086.com/

Validity: Nov.7, 2019 – Dec.31, 2020

Conclusion:
This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. CTC assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CTC is not affiliated with the U.S. Food and Drug Administration.

FDA Official Website: https://www.fda.gov/

CERTIFICATE

PAGE 2 of 2

ANNEX TO CERTIFICATION

| Listing Number | Premarket Submission Number | Product Code(s) | Device Name(s) / Proprietary Name | Activities |
|---|---|---|---|---|
| | Exempt | LRJ | Disinfectant, medical devices / Iodine swab | Manufacturer |
| | Exempt | KGX | Tape and bandage, adhesive / Medical Tape, Adhesive Bandage, Wound Plaster | Manufacturer |
| | Exempt | JES | FLOSS, DENTAL / Floss pick | Manufacturer |
| | Enforcement Discretion | OBR | Mouthguard, over-the- counter / Face Mask | Manufacturer |
| | Exempt | FQM | BANDAGE, ELASTIC / Elastic Bandage,Gauze Bandage | Manufacturer |
| | Exempt | IMD | PACK, HOT OR COLD, DISPOSABLE / Warm Patch, Cold Pack, Cool Patch, Fever Relief Patch, Cool gel, Freeze gel | Manufacturer |
| | Enforcement Discretion | LKB | Pad, alcohol, device disinfectant / Alcohol Wipes, Alcohol prep pad | Manufacturer |
| | Exempt | KXF | APPLICATOR, ABSORBENT TIPPED, NON-STERILE / Cotton Swab | Manufacturer |
| | Exempt | NAC | Dressing, wound, hydrophilic / Wound Dressing,I.V. Adhesive Dressing | Manufacturer |
| | Exempt | NAB | Gauze / sponge,nonresorbable for external use / Gauze Pad, Underpad, Cotton balls | Manufacturer |
| | Enforcement Discretion | OMO | First aid kit without drug / First aid kit | Manufacturer |

THIS ANNEX IS ONLY VALID IF ATTACHED TO THE CERTIFICATION MENTIONED ABOVE.

CERTIFICATE

TÜVRheinland

## Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

has established and applies a quality management system for medical devices for the following scope:

**Manufacture and Distribution of Sterile Wound Plasters, Sterile Wound Dressings, Medical Adhesive Tapes**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-09-10
Certificate Registration No.:
An audit was performed. Report No.:
This Certificate is valid until: 2021-09-07

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-09-10

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

## Contact Information

**Phone Number**
**+1 (312) 450-5043**

**Email**
**anatoliy@safedirectms.com**

**Office Address**
**1100 - 33 Yonge Street**
**Toronto, ON**
**M5E 0A9**