

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Fujian Nuomigao Medical Technology Co., Ltd.

Model Tested: KN95 Particulate Respirator – Willow Leaf Shaped (Black)

Date Tested: February 25, 2021

These findings pertain to the Fujian Nuomigao Medical Technology Co., Ltd., model KN95 Particulate Respirator – Willow Leaf Shaped (Black). The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found [here](#).

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 99.86% and 99.26%, respectively. All ten respirators measured more than 95% filter efficiency.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

**This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process.** This assessment was 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 due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for [Crisis Capacity Strategies \(during known shortages\)](#).

**Evaluation of International Respirators**

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** February 25, 2021

**Report Prepared:** February 25, 2021

**Manufacturer:** Fujian Nuomigao Medical Technology Co., Ltd.

**Item Tested:** KN95 Particulate Respirator – Willow Leaf Shaped (Black)

**Country of Certification:** China (GB2626-2006)

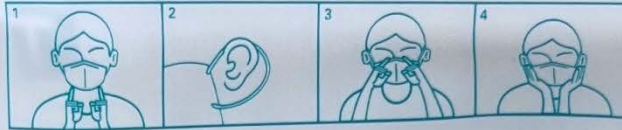
Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	11.5	0.65	0.65	99.35
2	85	11.9	0.41	0.44	99.56
3	85	16.8	0.14	0.14	99.86
4	85	11.3	0.51	0.51	99.49
5	85	12.0	0.61	0.61	99.39
6	85	15.6	0.16	0.16	99.84
7	85	15.9	0.74	0.74	99.26
8	85	14.8	0.20	0.20	99.80
9	85	16.5	0.19	0.19	99.81
10	85	16.6	0.14	0.14	99.86
<b>Minimum Filter Efficiency: 99.26%</b>			<b>Maximum Filter Efficiency: 99.86%</b>		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.



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## Instructions :

1. Position the respirator under your chin with the nose clip facing up.
2. Pull the straps behind your ears to fully cover your mouth and nose
3. Mold or pinch the nose clip around the nose with both hands and adjust the ear loops to ensure a proper seal.
4. Seal check:
  - a. Cup both hands completely over respirator and exhale sharply
  - b. If air flow is felt above the nose, re-adjust and tighten the nose clip as described in step 3.
  - c. If air flow is felt around the respirator edges, adjust the respirator/ear loops to achieve a better fit.

The respirator shall be discarded after one shift

## WARNINGS & LIMITATIONS:

- A. Failure to follow all instructions and limitations for using this respirator and / or not using it during the entire exposure period may reduce the respirator's effectiveness and result in illness or death.
- B. Before using, check that the respirator is in good operating condition. Check the integrity of all parts including straps, nose clip, material. The respirator must be discarded immediately if damaged or missing a component.
- C. Replace filtering respirator immediately if it becomes damaged, soiled, moist, or breathing becomes difficult.
- D. The filtering respirator shall be discarded after one shift.
- E. The respirator does not supply oxygen.
- F. Do not modify or misuse the filtering respirator.
- G. Do not use the filtering respirations in conditions that may prevent a good face-seal or else the requirements for leakage will not be achieved.
- H. Do not use the respirator to enter or stay in a contaminated area under the following circumstances:
  - a. Atmosphere contains less than 19.5% oxygen
  - b. If you smell or taste contaminant
  - c. For protection against gases or vapors
  - d. Contaminant of unknown concentrations or immediately dangerous to life or health
  - e. For sand blasting, paint-spray operations and asbestos
  - f. In explosive atmospheres
- I. This respirator helps protect against several particulate contaminants but does not completely eliminate risk of disease or infection. Misuse might lead to sickness or death.

Product Name: KN95 Particulate Respirator -Willow Leaf Shaped (Black)

Size : Folded Size 21.5 X 7.5CM ( ± 0.5CM )

Type: Disposable (Non-medical)

Executive Standard: GB2626-2006

Quantity: 2 pieces/bag

Production Date: See package

Lot No.: See package

SKU#: NKM101D

Usage: Provides protection against non-oily airborne particles (dust, sand, pollen) for individuals

Manufacturer: Fujian Nuomigao Medical Technology Co., Ltd.

Tel: 0086-595-85019885

Fax: 0086-595-85039885

Address: No.10 Lingshan Road, Economic Development Zone (Wuli Park), Jinjiang City, Fujian Province, China

Supplier: Watchtower PPE Supplies Inc., NY 11363

MADE IN CHINA

UPC-A: 850020210954

MFG DATE: 2020/07/23  
LOT NO.: 20200723



WTS PPE  
Supplies.



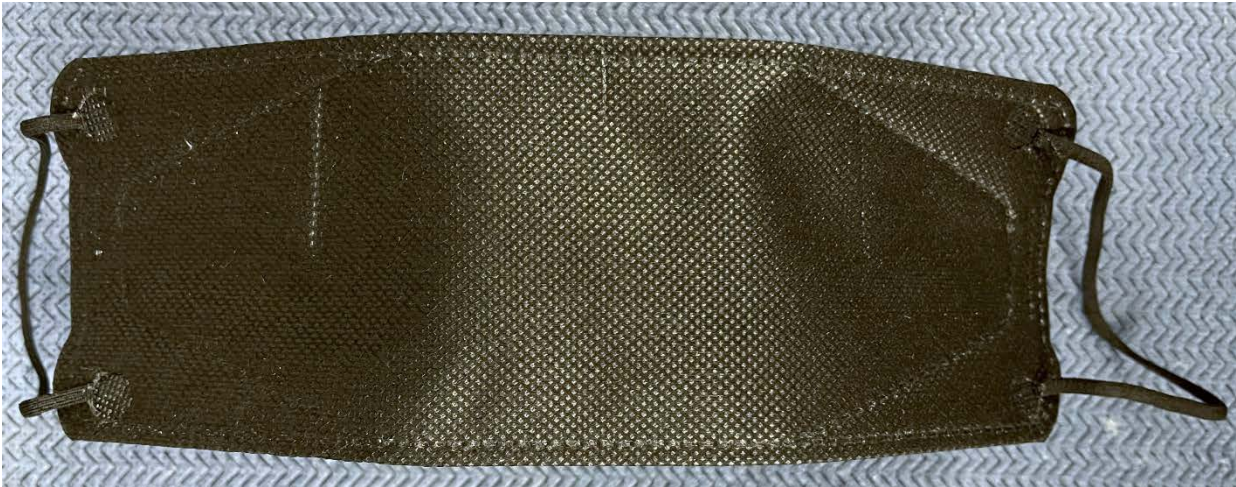
**合格证**  
**QUALITY CERTIFICATION**

【品名】KN95防护口罩-柳叶形(黑色)(非医用)  
【Product Name】KN95 Particulate Respirator-Willow Leaf Shaped(Black)(Non-medical)  
【数量】2片/袋  
【Quantity】2 pieces/bag  
【执行标准】GB 2626-2006  
【Executive Standard】GB 2626-2006  
【主要原材料】60%无纺布/40%熔喷布  
【Main Composition】60% Non-woven/40% Melt-blown fabric  
【产品规格】21.5cm x 7.5cm(±0.5cm)  
【Size】21.5cm x 7.5cm(±0.5cm)  
【生产日期/生产批号】见包装上  
【Production Date/Lot No.】Printed on package  
【保质期】2年  
【Validity】2 Years  
【生产企业】福建诺米高医疗科技有限公司  
【Manufacturer】Fujian Nuomigao Medical Technology Co.,Ltd.  
【地址】福建省晋江市经济开发区(五里园)灵山路10号  
【Address】No 10 Lingshan Road, Economic Development Zone  
(Wuli Park), Jinjiang City, Fujian Province, China.  
【电话】0086-595-85019885  
【Tel】0086-595-85019885

**诺米高医疗科技有限公司**  
**合格**  
**QC01**

中国制造  
MADE IN CHINA

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