

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhejiang Xingxin Medical Technology Co., Ltd.

Model Tested: KN95 Protective Face Masks

Date Tested: April 29, 2020

These findings pertain to the Zhejiang Xingxin Medical Technology Co., Ltd., KN95 Protective Face Masks. 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 observed was 98.81% and 90.93%, respectively. Nine respirators measured more than 95%. One respirator measured less than 95%.

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 respirator's 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: April 29, 2020

Report Prepared: May 5, 2020

Manufacturer: Zhejiang Xingxin Medical Technology Co., Ltd.

Item Tested: KN95 Protective Face Masks

Country of Certification: China (GB2626-2006)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	12.9	1.57	1.57	98.43
2	85	12.2	1.70	1.70	98.30
3	85	12.1	1.42	1.42	98.58
4	85	12.5	1.53	1.53	98.47
5	85	16.7	1.33	1.33	98.67
6	85	15.4	1.29	1.29	98.71
7	85	14.5	2.04	2.04	97.96
8	85	14.1	1.76	1.76	98.24
9	85	11.9	1.19	1.19	98.81
10	85	10.2	9.07	9.07	90.93
Minimum Filter Efficiency: 90.93			Maximum Filter Efficiency: 98.81		

- 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.

KN95 PROTECTIVE FACE MASKS

- High Filtration
- Low Drag
- Efficient Protection
- Bacterial Filtration

GB2626-2006

10pcs

• FITTING INSTRUCTION

1. Gently open the mask.
2. Hold the mask in front of the face with the nose clip facing upwards and away from you.
3. Attach each earloop behind the ears.
4. Press the middle of the nose clip inward to both sides until it is completely pressed into the shape of the bridge of the nose. Pinching the nose clip of the mask may affect its tightness.
5. Before entering the work area, check the tightness of the mask.

KN95 PROTECTIVE FACE MASKS

- **PRODUCT INFORMATION**

Product Name: Five-layer purification mask

Production Date: Shown in the package

Storage Conditions: Temperature -10°C – 40°C Relative humidity below 85%

- **MANUFACTURER**

ZHEJIANG XINGXIN MEDICAL TECHNOLOGY CO., LTD

No 430, Zhengjialou Village, Jinxiang Town, Cangnan County, Wenzhou City, Zhejiang Province, CN



KN95 PROTECTIVE FACE MASKS

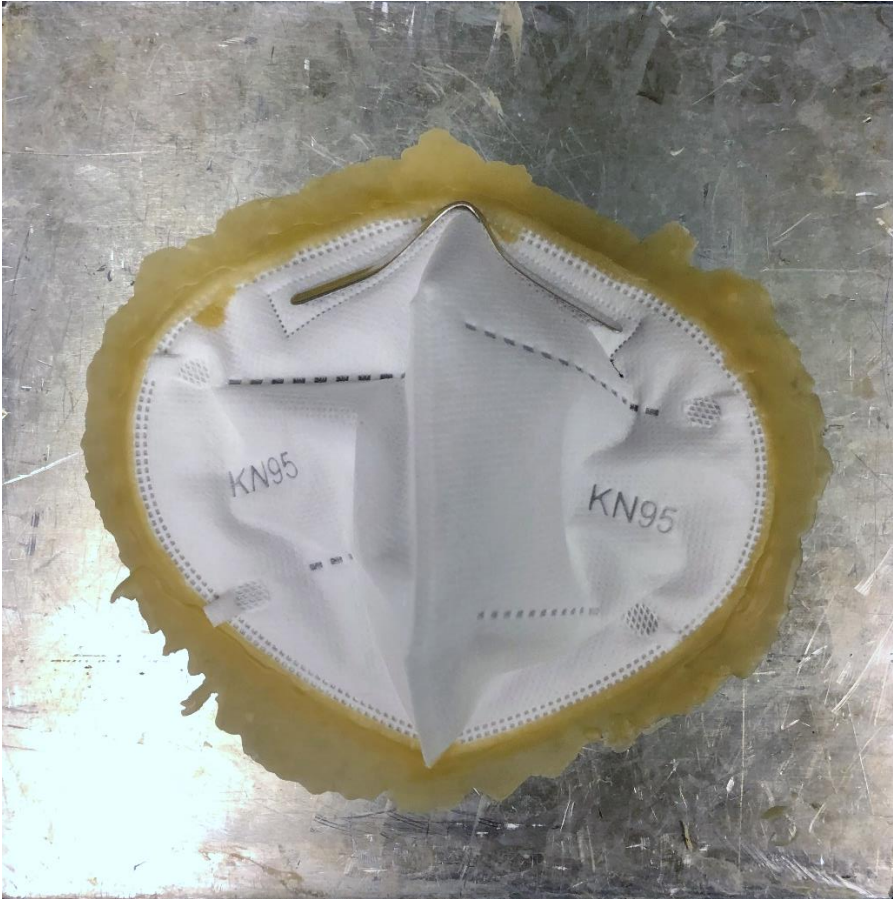
- **IMPORTANT INFORMATION**

1. Use the mask immediately after opening.
2. Do not use if the packaging is damaged or the seal broken.
3. This product is a disposable mask. It should not be cleaned or reused.
4. Throw a used mask away immediately and treat as a bio-hazard. Do not put a used mask back into the packaging.
5. If you experience difficulty breathing while using the mask remove it immediately and consult a physician.
6. For your safety only use the mask as instructed for its intended purpose.

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