

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: UNKNOWN

Model Tested: 3D Stereo Disposable Mask

Date Tested: August 17, 2020

These findings pertain to the respirators that were submitted for assessment. The manufacturer is unknown. The packaging and labeling indicate the models tested are KN95. However, there is no indication of what standard this product meets.

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 79.70% and 14.40%, respectively. All ten respirators 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: August 17, 2020

Report Prepared: August 17, 2020

Manufacturer: UNKNOWN

Item Tested: 3D Stereo Disposable Mask

Country of Certification: China (UNKNOWN)

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	3.2	77.1	78.0	22.00
2	85	3.1	79.0	80.7	19.30
3	85	2.4	85.1	85.6	14.40
4	85	2.9	80.4	83.4	16.60
5	85	8.7	20.3	20.3	79.70
6	85	1.8	78.5	82.0	18.00
7	85	2.9	78.8	81.6	18.40
8	85	3.0	78.9	84.2	15.80
9	85	2.1	77.4	78.3	21.70
10	85	2.9	80.9	83.4	16.60
Minimum Filter Efficiency: 14.40			Maximum Filter Efficiency: 79.70		

- 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.



A PROTECTION LEVEL $\geq 95\%$

FITTING INSTRUCTIONS



1. Please make sure the respirator side with the nose piece is facing toward your face, and the nosepiece is at the top edge of the mask, holding each ear loop with your hands.
2. Fit the mask to your face and under your chin.
3. Put the loops around your ears and adjust the ear loops to ensure the comfort level as much as possible.
4. Place your hands fingers in the middle of the nose piece and move our fingertips along the nose piece to both sides while pressing inward. Or it will impact the fit of the mask if users only use one hand to pinch the nose piece.
5. Before entering the work area, users must test the fit between the mask and face.
 - A. Place both hands over the respirator without disturbing its position.
 - B. If the respirator is not fitted with an exhalation valve, exhale sharply. If the respirator fitted with an exhalation valve, inhale sharply.
 - C. If you detect air-leaks, please follow the step 4 and readjust your nose piece; if the air leaks from the edge of the mask, please readjust the head straps and /or the position. If it does not work, please repeat the above steps.
 - D. If there are not air-leaks, you can enter the work area.

INSTRUCTIONS

1. It is necessary to choose makes properly. Users are supposed to receive professional training before fitting, so as to properly put on the respirator in a safe and healthy way.
2. This product does not offer oxygen, and it only can be used in a place with ventilation and adequate oxygen.
3. Please discard the respirator or wear a new one under the following circumstances:
 - A. Excessive clogging of the respirator causes breathing difficulty
 - B. The respirator becomes damaged.
4. Leave the contaminated area if dizziness, irritation or other distress occurs.



A PROTECTION LEVEL $\geq 95\%$

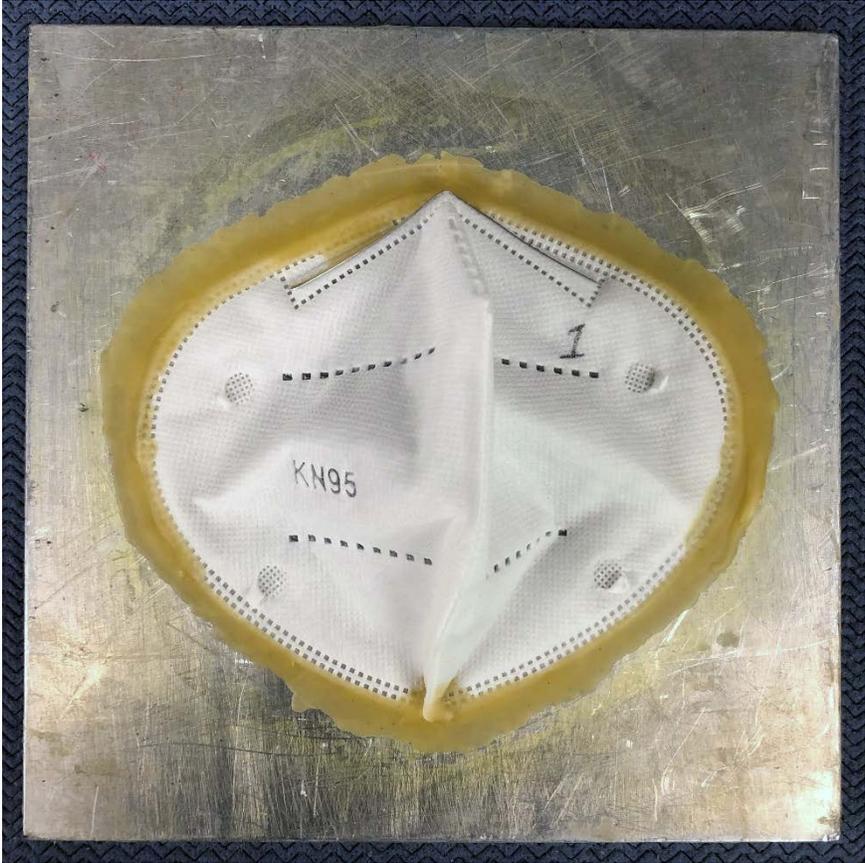
USE LIMITATIONS

1. Do not use the respirator in the case of low oxygen content, serious air pollution, bad breath or sleeping.
2. Users with severe asthma or other respiratory diseases shall be precautions for application.
3. Please use respirator properly. Do not exchange or abuse respirator, or it will cause serious consequences.
4. The temperature for storage should be $-20\text{ }^{\circ}\text{C}$ - $38\text{ }^{\circ}\text{C}$, and the relative humidity levels shall be less than 80%.

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