

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shenzhonghai Medical Inc.

Model Tested: 910

Date Tested: May 26, 2021

These findings pertain to the Shenzhonghai Medical Inc., model 910. The packaging and labeling for this product indicate that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Thirty respirators were submitted for evaluation. The samples were tested using the 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 98.99% and 89.11%, respectively. Twenty-five respirators measured more than 95% filter efficiency. Five respirators measured less 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: May 26, 2021

Report Prepared: May 26, 2021

Manufacturer: Shenzhonghai Medical Inc.

Item Tested: 910

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 | 11.0 | 1.90 | 2.08 | 97.92 |
| 2 | 85 | 13.5 | 1.92 | 1.92 | 98.08 |
| 3 | 85 | 17.7 | 2.40 | 2.40 | 97.60 |
| 4 | 85 | 8.7 | 3.72 | 3.87 | 96.13 |
| 5 | 85 | 9.4 | 5.26 | 5.45 | 94.55 |
| 6 | 85 | 8.8 | 2.52 | 2.89 | 97.11 |
| 7 | 85 | 7.9 | 8.85 | 8.86 | 91.14 |
| 8 | 85 | 11.0 | 2.44 | 2.55 | 97.45 |
| 9 | 85 | 9.0 | 4.00 | 4.29 | 95.71 |
| 10 | 85 | 13.7 | 7.55 | 7.55 | 92.45 |
| Minimum Filter Efficiency: 91.14% | | | Maximum Filter Efficiency: 98.08% | | |

- 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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|--|-----------------|--|--|-----------------------------|-----------------------|
| 11 | 85 | 8.8 | 3.21 | 3.62 | 96.38 |
| 12 | 85 | 12.5 | 1.89 | 1.96 | 98.04 |
| 13 | 85 | 7.8 | 10.67 | 10.89 | 89.11 |
| 14 | 85 | 15.4 | 1.11 | 1.11 | 98.89 |
| 15 | 85 | 14.3 | 1.30 | 1.30 | 98.70 |
| 16 | 85 | 8.6 | 2.12 | 2.45 | 97.55 |
| 17 | 85 | 9.7 | 2.50 | 2.75 | 97.25 |
| 18 | 85 | 12.1 | 2.37 | 2.51 | 97.49 |
| 19 | 85 | 13.2 | 2.72 | 4.09 | 95.91 |
| 20 | 85 | 10.9 | 2.46 | 2.55 | 97.45 |
| Minimum Filter Efficiency: 89.11% | | | Maximum Filter Efficiency: 98.89% | | |

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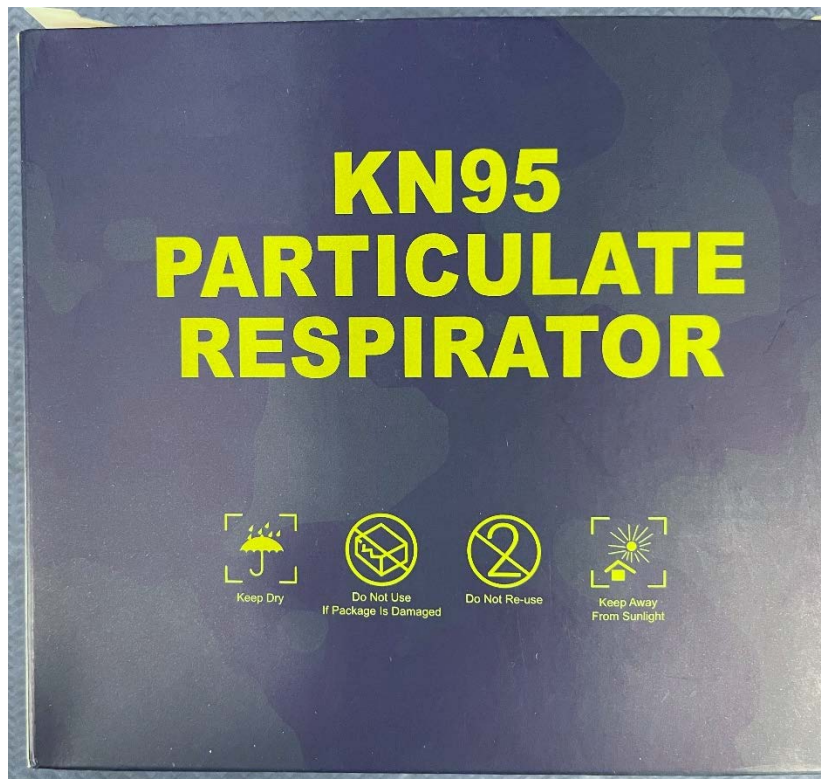
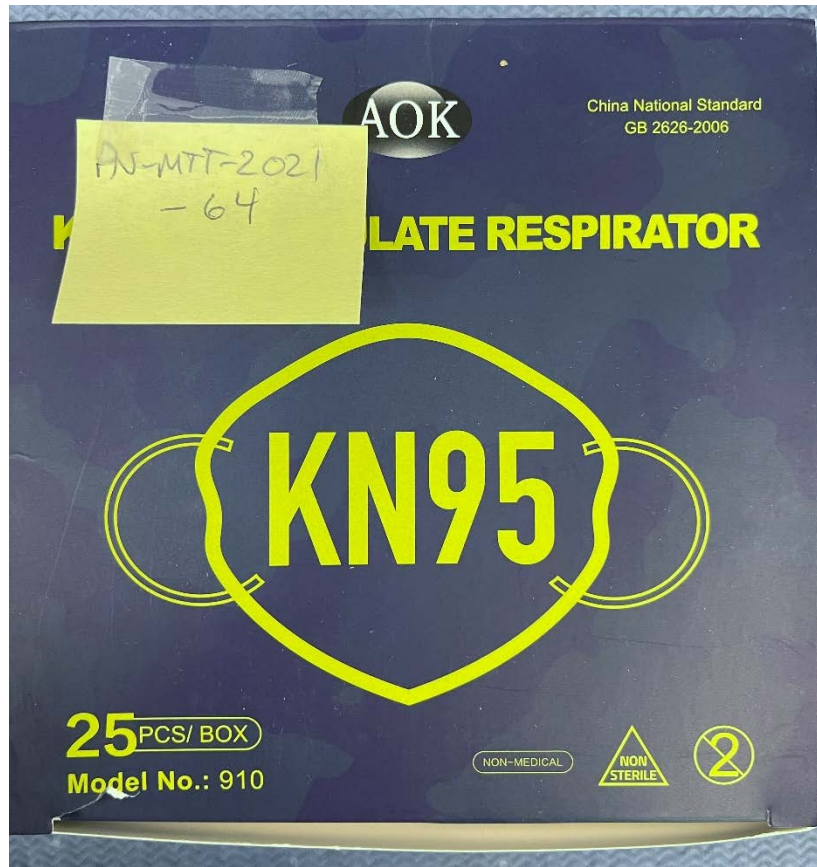
Item Tested: 910

Country of Certification: China (GB2626-2006)

| Filter | Flow Rate (LPM) | Initial Filter Resistance (mmH ₂ O) | Initial Percent Leakage (%) | Maximum Percent Leakage (%) | Filter Efficiency (%) |
|--|-----------------|--|--|-----------------------------|-----------------------|
| 21 | 85 | 12.0 | 4.41 | 4.41 | 95.59 |
| 22 | 85 | 10.4 | 2.99 | 3.25 | 96.75 |
| 23 | 85 | 8.9 | 0.99 | 1.01 | 98.99 |
| 24 | 85 | 11.8 | 2.87 | 2.87 | 97.13 |
| 25 | 85 | 17.2 | 1.22 | 1.22 | 98.78 |
| 26 | 85 | 8.6 | 0.97 | 1.04 | 98.96 |
| 27 | 85 | 11.4 | 5.47 | 5.47 | 94.53 |
| 28 | 85 | 11.5 | 1.29 | 1.29 | 98.71 |
| 29 | 85 | 10.7 | 3.76 | 4.17 | 95.83 |
| 30 | 85 | 9.7 | 3.68 | 3.73 | 96.27 |
| Minimum Filter Efficiency: 94.53% | | | Maximum Filter Efficiency: 98.99% | | |

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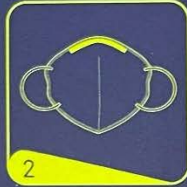
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How To Use:



Facing the respirator on the side of the silicone nose bridge. Nose clip metal facing upward.



Wear the mask close to your face. Adjust Ear Strap to a comfortable position.



Press the top and nose clip with index and middle fingers of both hands until feeling close to the nose bridge.



Cover the mask with both hands, test the positive and negative pressure to ensure that the mask is fit.

Compatibility Test:

- Positive pressure check: Gently press the mask with both hands, then deliberately exhale. The air should not leak from the edge of the mask.
- Negative pressure check: Gently press the mask with both hands, then deliberately inhale, the mask center should be depressed a little bit.
- If air enters through the edge of the mask, the Ear Strap and nose clip should be adjusted again.

Cautions:

- Please follow instructions to use the mask.
- Check package before use. Don't use if package is damaged.
- For single use only. Don't use the mask for more than 8 hours.
- Immediately change the mask if it is exposed to fluid or damages, or breathing resistance increases.
- The requirement for leakage will not be achieved if facial hair passes under the face seal.
- Check air quality (contaminants, oxygen deficiency). Don't use the mask in explosive atmosphere.

Product Information

Product Name: KN95 Particulate Respirator (NON-MEDICAL)

Model No.: 910 Size: L

Classification: KN95

Reference Standard: GB 2626-2006

Product Features: Foldable, ear straps, 3D design

Key Components of Product: The product consists of non-woven fabric, filter material, nose clip, and mask straps. Made by cutting, welding and packing.

Primary Materials: Seal ring (15%), non-woven (30%), meltblown non-woven (23%), electrostatic cotton (15%), protecting film (1%), nose piece+ear rope (16%)

Intended Use:

Protective nose and mouth covering to prevent the release of potential contaminants from the user into their immediate environment as well as protecting the wearer from large droplets, sprays and splashes of bodily fluids.

Product Performance: Filtration Efficiency: $\geq 95\%$




Instructions for Use:

1. Wear the mask close to your face. Adjust ear strap to a comfortable position.
2. Press the top and nose clip with index and middle fingers of both hands until feeling close to the nose bridge.
3. Cover the mask with both hands, test the positive and negative pressure to ensure that the mask is fit.

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Shelf Life: 2 years

Storage Conditions: Store in a dry and well-ventilated environment, temperature -30 C~40 C, relative humidity ≤ 85%

 Batch Code : 202006100100
 Date of Manufacture : 2020-06-10
 Use-by Date : 2022-06-09

Distributor: FINESENSE GLOBAL INC.
Add.: 2301 W Plano Pkwy, Suite 102, Plano TX 75075

Manufacturer: Shenzhonghai Medical Inc.
Add.: #8, Longtian 3Rd, Longtian Street, Pingshan Dist., Shenzhen, China
Tel: 86-0755-84112290

Made in China



See information supplied
by the manufacturer

25 PCS/ BOX



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