

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Senke Pharmaceutical (Chengdu) Co., Ltd.

Model Tested: KN95 Non-Powered Air-Purifying Particulate Respirator

Date Tested: May 1, 2020

These findings pertain to the Senke Pharmaceutical (Chengdu) Co., Ltd., KN95 Non-Powered Air-Purifying Particulate Respirator. The packaging and labeling for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator) and EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

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 98.36% and 92.19%, respectively. Seven respirators measured more than 95%. Three 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: May 1, 2020

Report Prepared: May 5, 2020

Manufacturer: Senke Pharmaceutical (Chengdu) Co., Ltd.

Item Tested: KN95 Non-Powered Air-Purifying Particulate Respirator

Country of Certification: China (GB2626-2006, EN149:2001+A1:2009)

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	4.83	4.83	95.17
2	85	10.1	7.81	7.81	92.19
3	85	10.9	2.56	2.56	97.44
4	85	10.1	5.03	5.03	94.97
5	85	8.7	5.63	5.63	94.37
6	85	10.5	1.64	1.64	98.36
7	85	10.5	2.09	2.09	97.91
8	85	9.7	3.22	3.22	96.78
9	85	9.6	3.82	3.82	96.18
10	85	10.9	1.73	1.73	98.27
Minimum Filter Efficiency: 92.19			Maximum Filter Efficiency: 98.36		

- 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.





INSTRUCTIONS



Unfold the mask with the nose clip side up. Hold the mask against your chin and snap it to your face.



Pull both ear straps behind your ears and hang them evenly on the ear, adjust the position of the earband and let the mask to cover your nose and mouth.



Place your fingertips on the nose clip and open it from the middle. Begin to press the nose clip, and gradually move to both sides, then shape the nose clip according to the bridge of the nose.



Cover the mask with both hands for positive pressure and negative pressure test to ensure the suitability of the mask.

CHECKING

Positive pressure check:
Gently press the mask with both hands, and then exhale intentionally. The air should not leak from the edge of the mask.

Negative pressure check:
Gently press the mask with both hands, and then inhale intentionally. The center of the mask should be slightly sunken.

If there is air leakage, adjust the nose clip, ear strap, and the position of the mask, until it no longer leaks.

PRECAUTIONS

1. Please check the packaging and masks for damage before use. Do not use if broken.
2. Do not wash this product and pay attention to moisture. Do not place after wearing, it is easy to get wet in a sealed plastic bag.
3. In case of liquid splashing, damage to the mask, dampness, and increased respiratory resistance during wearing, please change it in time.
4. When you feel difficulty breathing, dizziness or other discomforts, please leave contaminated area immediately.
5. Not applicable for non-woven allergies

STORAGE CONDITIONS

1. It is recommended to store at temperature between -30°C-40°C, and the maximum relative humidity not more than 80%.
2. Keep in the clean room with good ventilation.
3. Avoid mechanical squeeze, moisture, high temperature, sunlight and corrosive chemical.

[Batch No.]	263404
[Production Date]	2020.04.04
[Shelf Life]	2 years

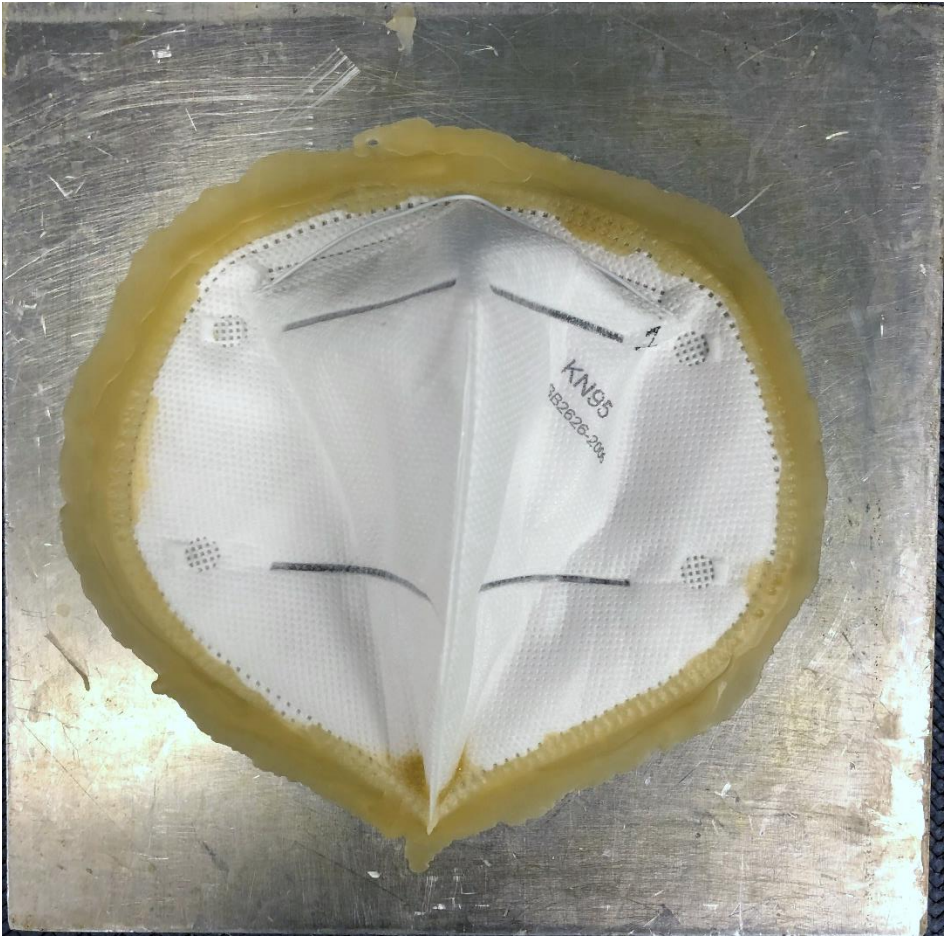
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