

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shenzhen Sanai Medical Devices Group Co., Ltd.

Model Tested: Disposable Protective Mask

Date Tested: May 7, 2020

These findings pertain to the Shenzhen Sanai Medical Devices Group Co., Ltd., Disposable Protective Mask. 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 90.04% and 86.00%, 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: May 7, 2020

Report Prepared: May 8, 2020

Manufacturer: Shenzhen Sanai Medical Devices Group Co., Ltd.

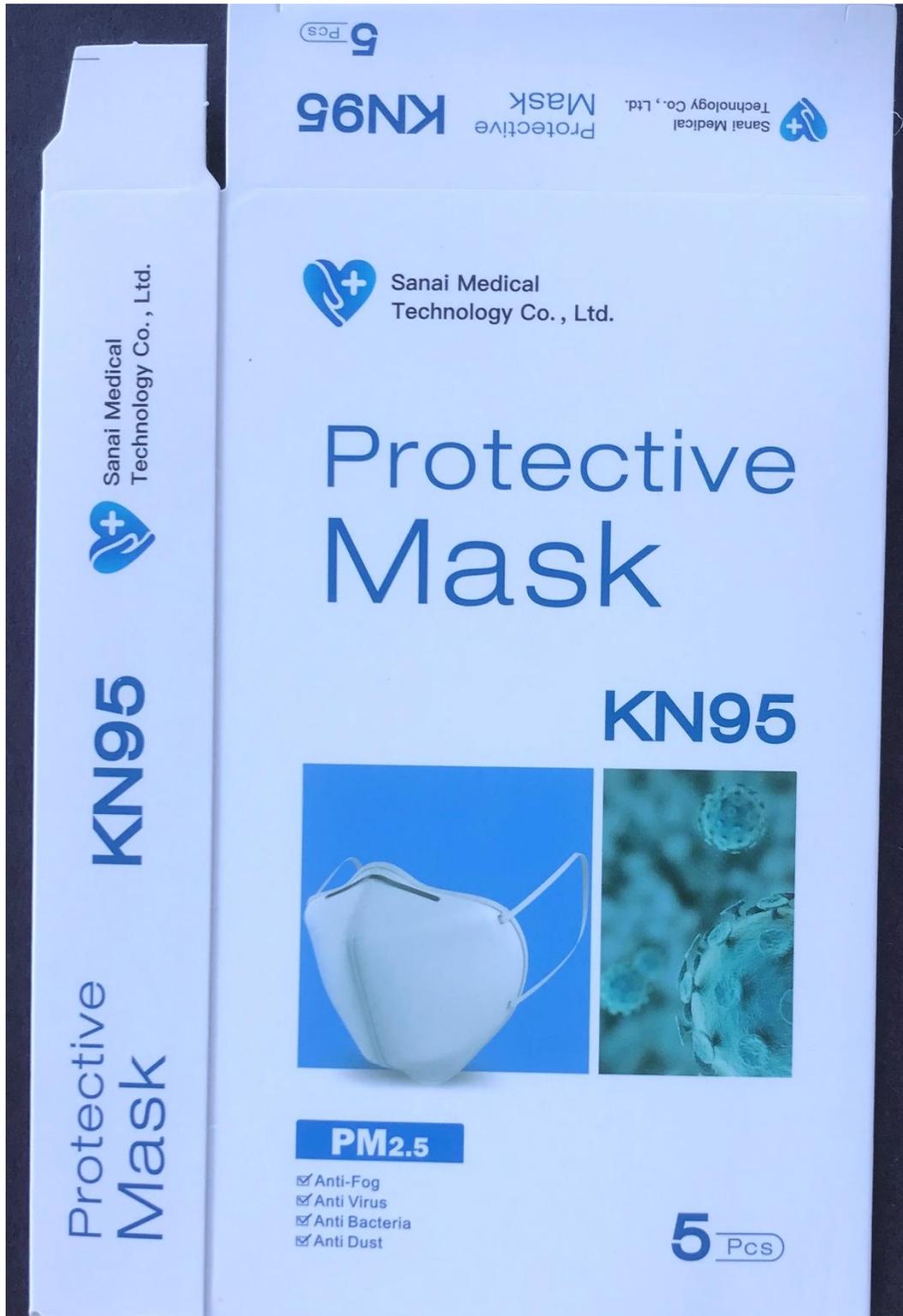
Item Tested: Disposable Protective Mask

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	10.1	9.96	9.96	90.04
2	85	9.9	10.2	10.2	89.80
3	85	10.2	10.2	10.2	89.80
4	85	9.8	11.5	11.5	88.50
5	85	9.4	14.0	14.0	86.00
6	85	10.3	12.0	12.0	88.00
7	85	10.4	13.7	13.7	86.30
8	85	11.0	13.9	13.9	86.10
9	85	10.2	10.3	10.3	89.70
10	85	10.0	12.5	12.5	87.50
Minimum Filter Efficiency: 86.00			Maximum Filter Efficiency: 90.04		

- 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.



Sanai Medical
Technology Co., Ltd.



KN95

Protective
Mask

INSTRUCTIONS FOR USE

- Open the package, take the mask out, and make sure the mask is intact.
- Put the mask on your face with the nose clip upwards, ensure the white side of the mask touches your mouth and adjust it to ensure comfort. Please do avoid direct contact with the white side of the mask.
- Gently pinch the nose clip to fit the shape of your nose. Keep pinching the nose clip, and at the same time adjust the lower end of the mask over your mouth and chin, to make sure it fits closely.



PRECAUTIONS

- This is a single-use mask, please do not reuse it;
- Do not use it if the package or mask is damaged or broken;
- People allergic to non-woven fabrics must use this mask cautiously.
- Replace the mask if the respiratory resistance is significantly enhanced (breathing is difficult), or the mask is contaminated (stained with foreign matter such as blood or droplets).

PRODUCT INFORMATION

Product Name: Disposable protective mask
Production date: See the packaging label
Term of validity: 24 months
Executive standard: GB2626-2006
Main raw materials: Non-woven fabric, melt blown fabric
Storage method: Please store in a dry and ventilated environment, Storage temperature: -10 °C ~ 40 °C, relative humidity less than 90%
Supervised by: Shenzhen Sanai Medical Devices Group Co., Ltd.
Production address: Sanai Science and Technology Park, No. 210, Yuejin Road, Xibin town, Jinjiang City, Quanzhou, Fujian Province



KEEP AWAY FROM SUNLIGHT

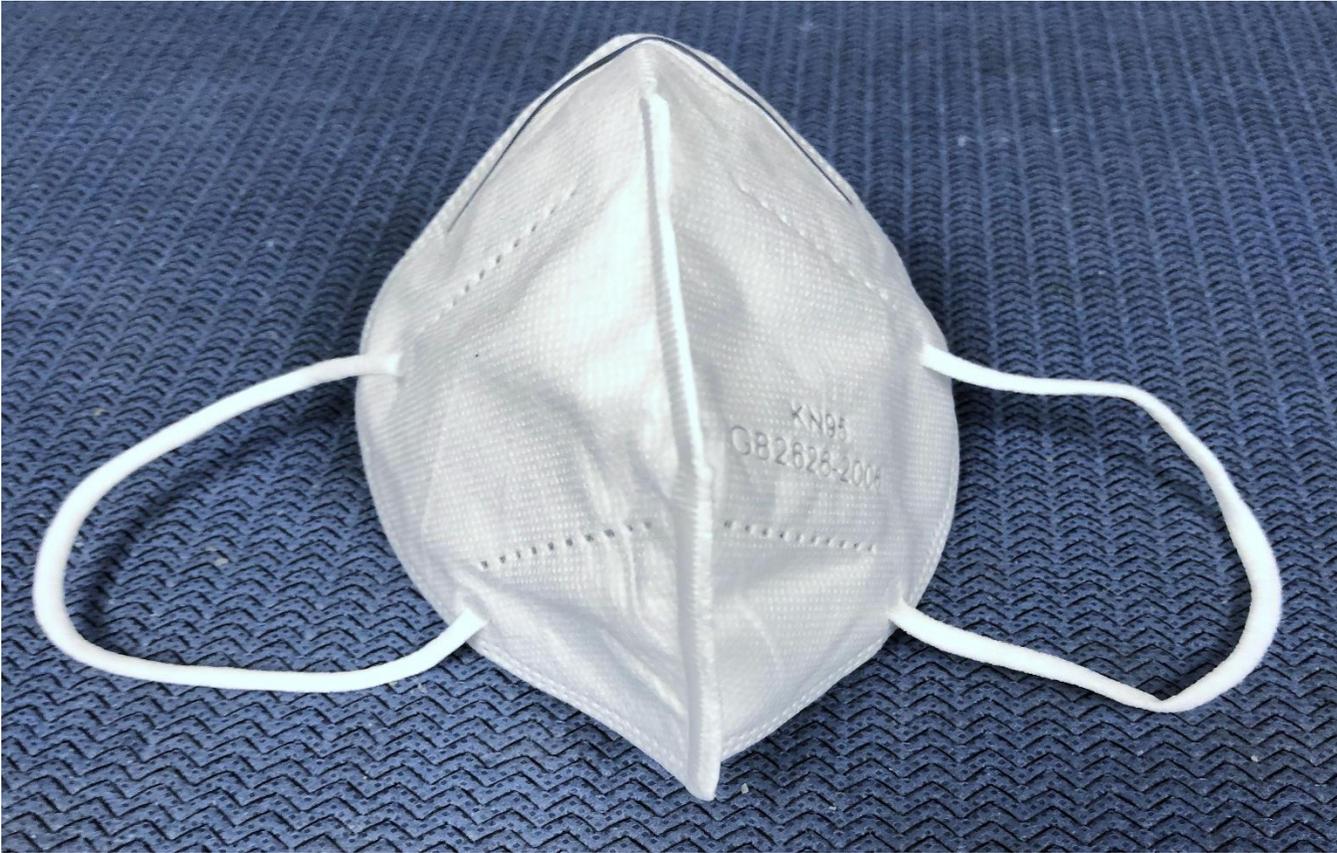


Protective
Mask

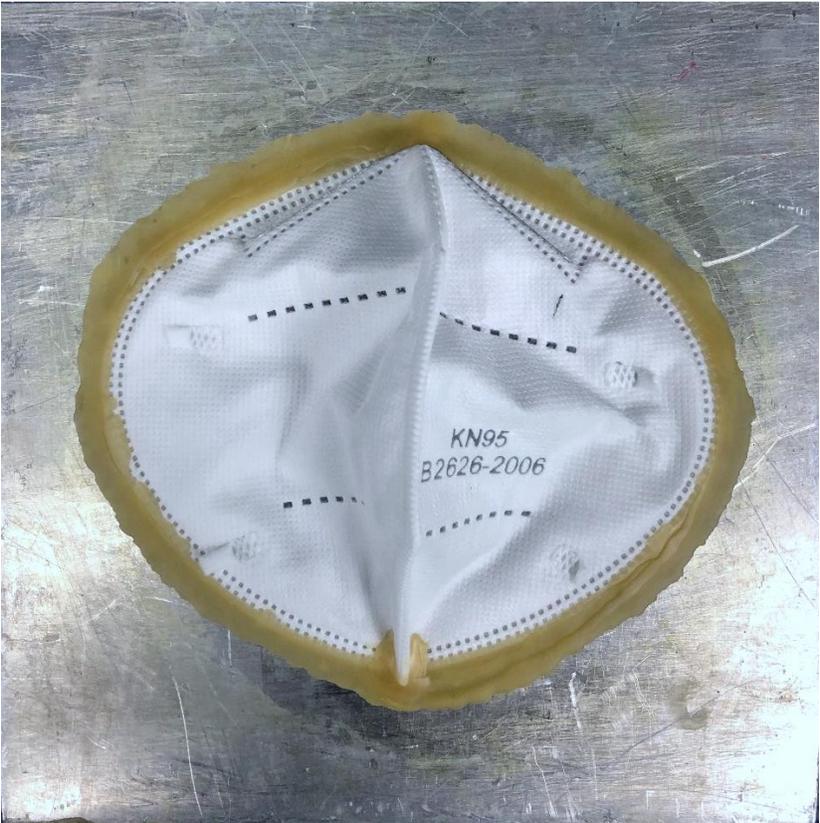
KN95

5 Pcs

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