

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Anshun Health & Medical Technology Co., Ltd.

Model Tested: AKF2002

Date Tested: May 30, 2020

These findings pertain to the Anshun Health & Medical Technology Co., Ltd., model AKF2002. 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 98.75% and 96.12%, respectively. All ten respirators measured more 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 30, 2020

Report Prepared: May 30, 2020

Manufacturer: Anshun Health & Medical Technology Co., Ltd.

Item Tested: AKF2002

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	12.5	3.72	3.72	96.28
2	85	15.4	3.34	3.34	96.66
3	85	16.4	2.54	2.54	97.46
4	85	23.8	1.25	1.25	98.75
5	85	13.8	3.53	3.53	96.47
6	85	16.6	2.04	2.04	97.96
7	85	14.7	3.59	3.59	96.41
8	85	17.5	3.88	3.88	96.12
9	85	19.9	2.30	2.30	97.70
10	85	18.0	2.44	2.44	97.56
Minimum Filter Efficiency: 96.12			Maximum Filter Efficiency: 98.75		

- 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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USER INSTRUCTIONS

- 1 Failure to follow all instructions and limitations could seriously reduce the effectiveness of this particle filtering half mask and could lead to illness, injury or death.
- 2 A properly selected respirator is essential, before occupational use, the wearer must be trained by the employer in the correct use of the respirator in accordance with applicable safety and health standards.
- 3 This particle filtering half mask does not supply oxygen. Use it in adequately ventilated and where containing sufficient oxygen to support life.
- 4 Discard the respirator and replace with a new one if:
 - a. Excessive clogging of the particle filtering half mask cause breathing difficulty.
 - b. The particle filtering half mask become damaged
- 5 Leave the contaminated area if dizziness, irritation or other distress occurs

FITTING INSTRUCTION

- 1 Place fingers inside the particle filtering half mask. Bend the nose clip around fingers to form nose shape
- 2 Hold the particle filtering half mask in position over the nose and mouth, pull the head harness behind the ears.
- 3 Use both hands, form the nose clip around the nose and shift the head harness to ensure a positive face seal.
- 4 Seal check
 - a. To test the fit of the particle filtering half mask without an exhalation valve, cup both hands over particle filtering half mask and inhale sharply.
 - b. If air flow is felt in the nose area, re-adjust and tighten the nose clip.
 - c. If are flows is felt around the edges of the respirator, adjust the particle half particle filtering half mask /head harness to achieve a better fit
- 5 Change the particle filtering half mask immediately if breathing becomes difficult or particle filtering half mask becomes damaged or distorted
- 6 Change the particle filtering half mask if proper face seal cannot be achieved
- 7 Carefully observe these instructions is an important step in safe respirator use

Model: AKF2002

USE LIMITATIONS

- 1 Do not use the respirator or enter or stay in a contaminated area under the following circumstance:
 - a. Atmosphere contains less than 19.5% oxygen.
 - b. If you smell or taste contaminant
 - c. For protection against gases or vapors
 - d. Contaminants or their concentrations are unknown or immediately dangerous to life or health.
 - e. For sandblasting, paint-spray operations and asbestos.
 - f. In explosive atmospheres
- 2 Do not modify or misuse the particle filtering half mask
- 3 Do not use the particle filtering half mask with facial hair or any other conditions that may prevent a good face-seal, the requirements for leakage will be achieved
- 4 Particle filtering half mask need to be inspected prior to each use to assure there are no holes in the breathing zone other than punctures around and staples and no damaged has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage.
- 5 This respirator helps protect against certain particulate contaminants but does not eliminate exposure to out the risk of contracting disease or infection. Misuse may result to sickness or death
- 6 This particle filtering half mask marked "NR", shall not be used for more than one shift
- 7 This particle filtering half mask is not suitable for users has an ear that has been damaged.

Temperature range of conditions

Maximum relative humidity of storage conditions

See information supplied by the manufacturer

Manufacturer: Anshun Health And Medical Technology Co., Ltd.
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xixiu district, anshun city, Guizhou province, China.

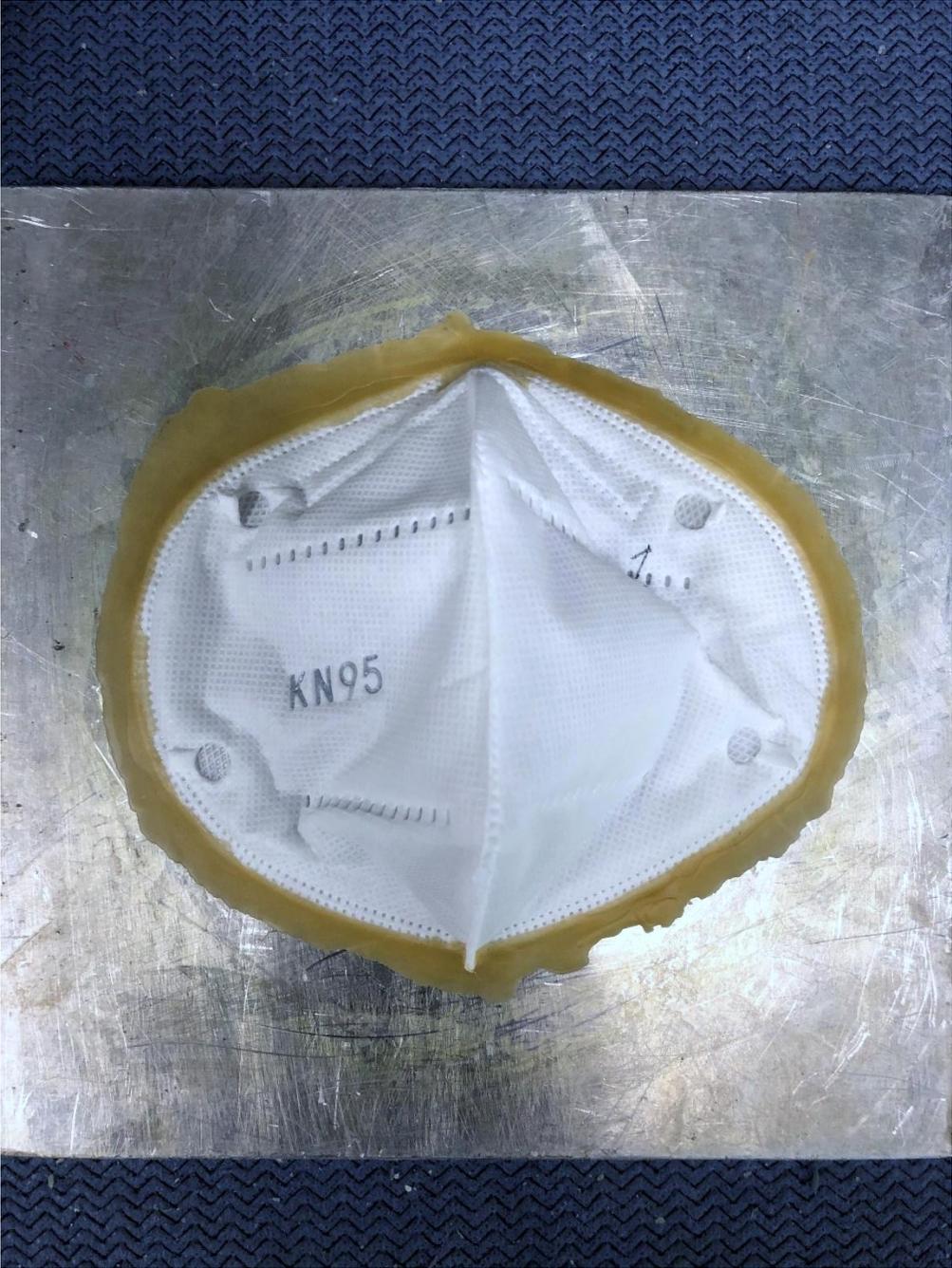
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