

NPPTL COVID-19 Response: International Respirator Assessment

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

Model Tested: AKF2002

Date Tested: June 11, 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 98.84% and 96.29%, 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: June 11, 2020

Report Prepared: June 11, 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	15.5	2.12	2.12	97.88
2	85	11.6	1.16	1.16	98.84
3	85	11.2	1.26	1.26	98.74
4	85	18.1	2.02	2.02	97.98
5	85	12.4	2.06	2.06	97.94
6	85	9.6	2.45	2.45	97.55
7	85	14.0	1.82	1.82	98.18
8	85	10.7	1.26	1.27	98.73
9	85	13.3	3.71	3.71	96.29
10	85	17.4	1.31	1.31	98.69
Minimum Filter Efficiency: 96.29			Maximum Filter Efficiency: 98.84		

- 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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(Production Name): KN95 Protective Mask

(Size): 15.5X10.5cm

(Implementation Standard): GB2626-2006

(Material Quality): Filter layer of melt-blown cloth and Inner and outer layer of pp non-woven fabric

(Quantity): 50 PIECES/PACK

(Shelf Life): Three years

(Storage): Temperature 20 C -40 C ,relative humidity less than 80%

(Production Date): Packaging

(Manufacturer): Anshun Health And Medical Technology Co.,Ltd

(Address) : 1F,E6 building industry science and technology park,xixiu district,Anshun city,Guizhou province,China.

MADE IN CHINA



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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 respirator face mask
3. Do not use the respirator face mask with facial hair or any other conditions that may prevent a good face-seal, the requirements for leakage will be achieved
4. Respirator face 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. Enlarge 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 respirator face mask marked "NR", shall not be used for more than one shift
7. This respirator face mask is not suitable for users has an ear that has been damaged.

合格证 CERTIFICATION

产品名称: 一次性防护口罩
Name: KN95 Protective Mask

型号: AKF2002
Model:

执行标准: GB2626-2006
Executive standards:

产品规格: 15.5x10.5cm
Product specifications:

产品材料: 71%无纺布, 29%熔喷布
Product material: 71% non-woven fabric, 29% melt-blown fabric

生产批号/ Batch number: 20200509

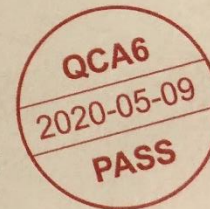
生产日期/ Production Date: 2020/05/09

有效期/ Shelf life: 3 years

检验员/ Inspector: A02

生产企业: 安顺市安康福医疗科技有限公司
Manufacturer: Anshun Health And Medical Technology Co.,Ltd

生产地址: 贵州省安顺市西秀区六路产业科技园E6栋厂房
Registration address: 1F,E6 building industry science and technology park,xixiu district,Anshun city,Guizhou province,China.



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