

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Hefei Kadi Biological Pharmaceutical Co., Ltd.

Model Tested: Non-Medical Protective Mask

Date Tested: July 29, 2020

These findings pertain to the Hefei Kadi Biological Pharmaceutical Co., Ltd., Non-Medical 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 97.77% and 94.03%, respectively. Two of the 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 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: July 29, 2020

Report Prepared: July 31, 2020

Manufacturer: Hefei Kadi Biological Pharmaceutical Co., Ltd.

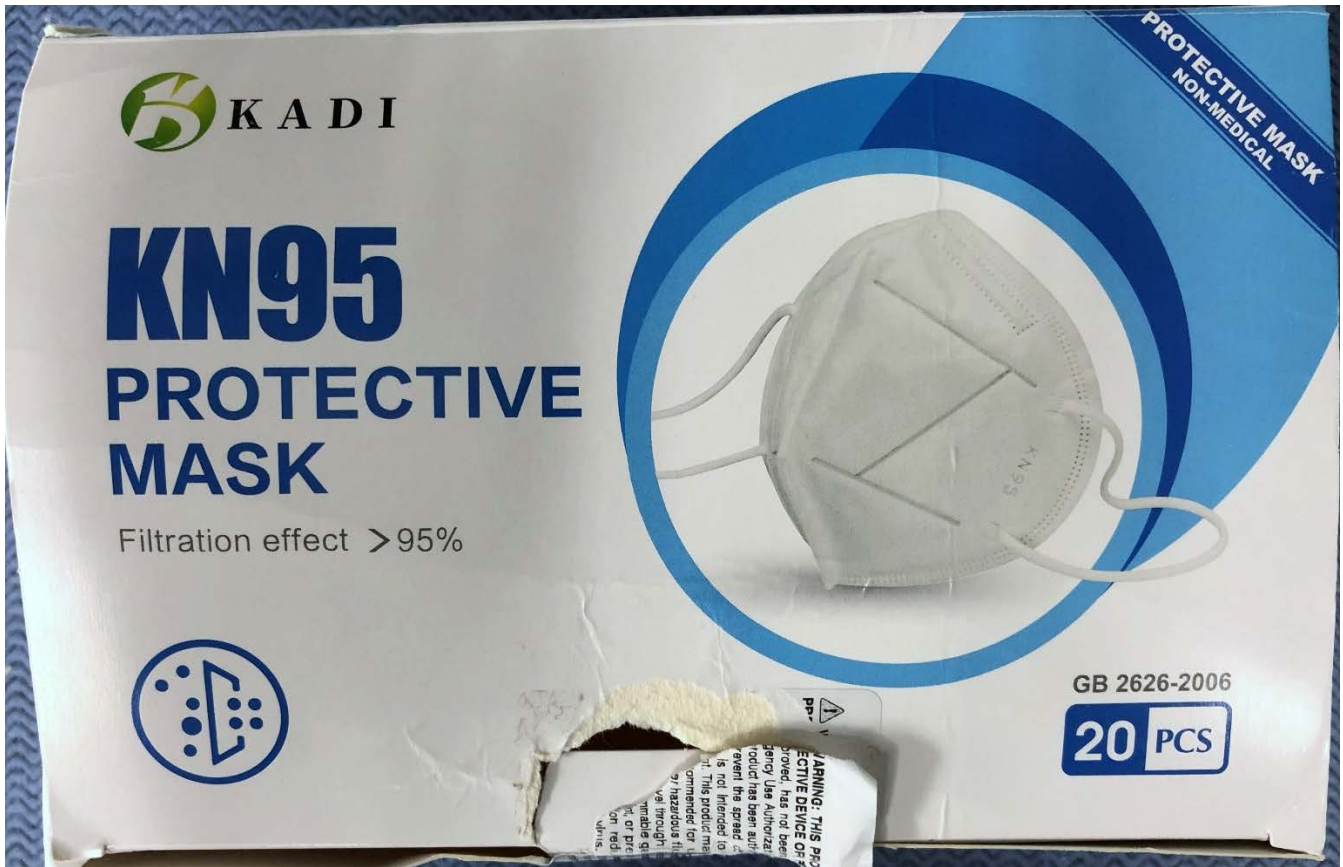
Item Tested: Non-Medical Protective Mask

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	9.4	2.23	2.23	97.77
2	85	9.7	2.76	2.76	97.24
3	85	7.8	5.08	5.97	94.03
4	85	8.8	2.85	2.85	97.15
5	85	8.6	3.14	3.14	96.86
6	85	7.9	3.30	3.30	96.70
7	85	10.0	4.42	4.42	95.58
8	85	8.7	5.88	5.88	94.12
9	85	8.9	3.68	3.68	96.32
10	85	10.0	2.72	2.72	97.28
Minimum Filter Efficiency: 94.03			Maximum Filter Efficiency: 97.77		

- 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.



STEPS TO WEAR A MASK



1. Open the mask, facing the side of the mask without the nose clip, and pull the ear straps with both hands.
2. Hold the mask against the chin so that the nose clip is above the mask.
3. After straightening the ear band, adjust the ear band to a comfortable position.
4. Press the metal nose clip so that the metal clip fits the shape of the bridge of the nose.
5. Check if you are qualified: Press the mask lightly with both hands, and then breathe in deliberately.

【 Manufacturer 】 Hefei Kadi Biological Pharmaceutical Co., Ltd.

【 Domicile of production enterprise 】 2nd Floor, No.3 Building, Workshop 3, Xiwei SanRd., Feidong Economic Development Zone, Hefei, Anhui, China

【 After sales service unit 】 Hefei Kadi Biological Pharmaceutical Co., Ltd.

【 Contact information 】 0551-62528565

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[Product structure] The product is composed of mask body, nose clip and mask belt. The filter material of mask body is polypropylene melt spray cloth.

[Usage method] 1. Place the mask on the lower half of the face, and hang the ear rope outward. 2. Press the nose strip to make sure it is fully attached, pull down the lower end of the mask to cover the lower jaw, hang the ear rope on the back of the ear, and finally make sure that the mask has completely covered the lower half of the face and obtained the maximum protection effect.

[Matters needing attention] The filtration efficiency of the product for non oily particles is $\geq 95\%$, please do not exceed the scope of use; the product is non sterile product, disposable; it should be used as soon as possible after opening the package; after using the product, please properly dispose; do not use the product whose package is damaged or invalid.

[Storage conditions and methods] It shall be stored in a dry, ventilated and non corrosive environment, away from fire sources and inflammables.

[Term of validity] Two years

LOT NO.:

M20200401

MFG. DATE.:

20200403

EXP. DATE.:2 YEARS

EXECUTIVE STANDARD:GB 2626-2006





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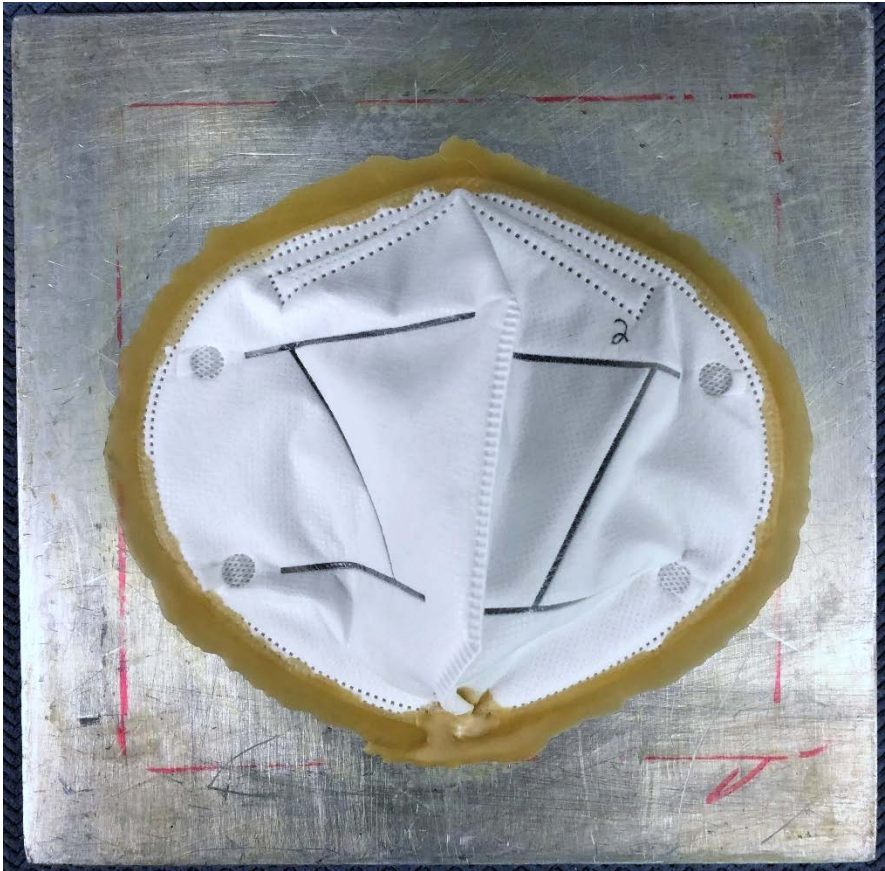
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合肥卡迪生物药业有限公司 HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO.,LTD	
合格证	
品名 Product name	防护口罩 (非医用) Non-Medical Protective Mask
执行标准 Executive Standard	GB2626-2006
产品规格 Product Specification	KN95
主要成份 Composition	无纺布45%, 热风棉26%, 熔喷布26%, 氨纶3% non-woven fabric 45%, hot air cotton 26%, meltblown 26%, spandex 3%
包装规格 Package specification	20个/盒; 50盒/箱 20pcs/box; 50 boxes/carton
生产批号 Batch Number	M20200401
生产日期 Manufacturing Date	2020年4月3日
保质期 Valid time	2 years
检验员 Inspector	01
地址 Address	安徽省肥东县经济开发区西外环西纬三路北侧3#厂房003栋 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd., Feidong Economic Development Zone, Hefei, Anhui, China
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