

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Hangzhou Biopharmaceutical National High-tech Industrial Base Investment Management Co., Ltd.

Model Tested: 9501

Date Tested: July 30, 2020

These findings pertain to the Hangzhou Biopharmaceutical National High-tech Industrial Base Investment Management Co., Ltd., Model 9501. 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 99.36% and 95.04%, respectively. No 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 30, 2020

Report Prepared: July 31, 2020

Manufacturer: Hangzhou Biopharmaceutical National High-tech Industrial Base Investment Management Co., Ltd.

Item Tested: 9501

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 | 11.5 | 1.18 | 1.18 | 98.82 |
| 2 | 85 | 18.7 | 4.96 | 4.96 | 95.04 |
| 3 | 85 | 12.7 | 0.64 | 0.64 | 99.36 |
| 4 | 85 | 16.0 | 3.93 | 3.93 | 96.07 |
| 5 | 85 | 18.6 | 4.75 | 4.75 | 95.25 |
| 6 | 85 | 17.4 | 4.06 | 4.06 | 95.94 |
| 7 | 85 | 18.0 | 4.27 | 4.27 | 95.73 |
| 8 | 85 | 12.0 | 0.93 | 0.93 | 99.07 |
| 9 | 85 | 11.9 | 0.96 | 0.96 | 99.04 |
| 10 | 85 | 11.6 | 0.98 | 0.98 | 99.02 |
| Minimum Filter Efficiency: 95.04 | | | Maximum Filter Efficiency: 99.36 | | |

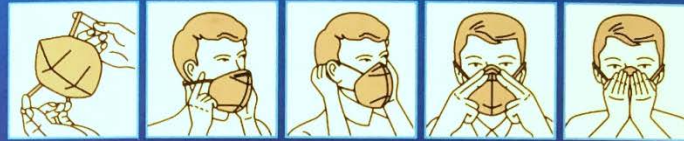
- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested 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.



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Inspection Method

Before use, check whether the packaging of the mask is damaged and whether the components are normal. If there is any stain or damage, stop using it. Before entering the work area, you must check the tightness of the mask and the face. If you feel the leak, please re-wear it; if you do not feel the leak, you can enter the work area to work. (When the respiratory resistance is significantly increased or the mask does not meet the required standards, it is recommended to replace the product)



Wearing Method

1. Face the face of the mask without the nose clip, and pull the ear straps with both hands so that the nose clip is above the mask.
2. Cover your chin with a mask.
3. Pull the ear strap behind your ear and adjust the ear strap to feel as comfortable as possible.
4. Place the fingers of both hands in the middle of the nose clip, press one hand inward, and move the fingertips along the nose clip to the sides until the nose clip is fully pressed into the shape of the bridge of the nose. Using only one hand to pinch the mask nose clip may affect the tightness of the mask.
5. Before entering the work area, the user must check the tightness of the mask to the face:
 - a) Cover the mask with both hands to avoid affecting the position of the mask on the face.
 - b) If the mask has no exhalation valve, exhale quickly; if the mask has an exhalation valve, inhale quickly.
 - c) If the air leaks from the bridge of the nose, readjust the nose clip according to step 4.
 - d) If the air leaks from the edge of the mask, readjust the earband; if a good fit cannot be achieved, repeat steps 1-4.

Precautions

- This product is a self-priming filter type anti-particulate respirator
- Cannot be used when the ambient temperature exceeds 50 degrees
- Cannot be used when the ambient oxygen content is lower than 19.5%
- Cannot be used in a toxic gas environment (not a substitute for a gas mask)
- Respiratory protection for non-oily particles only
- Because the mask has some breathing resistance, it is not recommended for Children, pregnant women, and the elderly

Can be used for protection

Particulate matter generated during grinding, sanding, cleaning, sawing, bagging, etc., or during the processing of ore, coal, iron ore, flour, metal, wood, pollen and some other substances, does not emit oily gas Sol or vapor liquid or non-oily particles produced by spray

Not for protection

Gases and vapors, oily aerosols, asbestos, arsenic, cadmium, lead, 4,4'-diaminodiphenylmethane (MDA) or sandblasting at concentrations exceeding 10 times the permitted exposure limit or occupational exposure limit (PEL / OEL) US Occupational Safety and Health Administration (OSHA) special substance standards or applicable government regulations, whichever is lower, this protective mask does not generate oxygen

Applicable industry

Suitable for casting, laboratory, primer, cleaning and sanitation, chemical pesticide, solvent cleaning, spray printing, electroplating, electronics, food processing industry, automobile and ship building, ink dyeing and finishing, environmental disinfection.

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产品名称: 自吸过滤式防颗粒物呼吸器
型号: 9501型
规格: 随弃式面罩 无呼气阀 KN95 50只/盒
主要成份: 无纺布、熔喷过滤材料
执行标准: GB2626-2006 KN95
生产日期: 见外包装
保质期: 一年
建议储存条件: 湿度 <80%, 无腐蚀性气体和通风良好的清洁室内
包装破损, 禁止使用。使用前请参见制造商提供信息

Product name: KN95 particulate protective mask
Model : 9501
Specifications: disposable mask without exhalation valve type KN95
Quantity: 50 pieces
Main ingredients: non-woven fabric, meltblown filter material
Executive standard: GB2626-2006 KN95
Production date: See packaging
Shelf life: one year
Recommended storage conditions: humidity <80%, non-corrosive gas and well-ventilated clean room.
**The packaging is damaged and prohibited to use.
See the manufacturer's information before use**



警告

本产品只用于对某些颗粒物的呼吸防护。错误使用可导致疾病甚至死亡。欲了解正确使用方法, 请参见包装上制造商提供的信息。使用前请参见制造商提供信息

检查方法:

使用前检查口罩的包装是否破损, 元件是否正常; 如有污渍、破损, 请停止使用。在进入工作区域之前, 必须检查口罩与脸部的密合性。如果感觉泄漏, 请重新佩戴, 如没有感觉泄漏, 方可进入工作区工作。(当感觉呼吸阻力明显增加时或者口罩达不到需要的标准, 建议更换产品)

佩戴方法:



1. 面向口罩无鼻夹的一面, 两手各拉住一边耳带, 使鼻夹位于口罩上方。
2. 用口罩抵住下巴。
3. 将耳带拉至耳后, 调整耳带至感觉尽可能舒适。
4. 将双手指置于鼻夹中部, 一边向内按压一边顺着鼻夹向两侧移动指尖, 直至将鼻夹完全按压成鼻梁形状为止。仅用单手捏口罩鼻夹可能会影响口罩的密合性。
5. 在进入工作区域之前, 使用者必须检查口罩与脸部的密合性:
 - a) 用双手罩住口罩, 避免影响口罩在脸上的位置。
 - b) 如口罩无呼气阀, 快速呼气; 如口罩带呼气阀, 快速吸气。
 - c) 如空气从鼻梁处泄漏, 应按步骤4重新调整鼻夹; 如空气从口罩边缘泄漏, 应重新调整耳带; 如不能取得良好的密合, 应重复步骤1-4。
 - d) 如没有感觉泄漏, 可进入工作区工作。

注意事项:

- 本产品为自吸过滤式防颗粒物呼吸器
- 不能在环境温度超过50度情况下使用
- 不能在环境含氧量低于19.5%情况下使用
- 不能在有毒气体环境下使用(不能代替防毒面具)
- 仅适用于非油性颗粒物的呼吸防护
- 因为口罩存在一定的呼吸阻力,故不建议儿童、孕妇、老人佩戴

可用于防护:

在研磨、砂纸打磨、清洁、锯切、装袋等过程中,或在矿石、煤、铁矿、面粉、金属、木材、花粉和某些其他物质的加工过程中产生的颗粒物,不散发油性气溶胶或蒸汽的由喷雾产生的液态或非油性的颗粒物。

不可用于防护:

气体和蒸汽、油性气溶胶、石棉、砷、镉、铅、4,4'-二氨基二苯基甲烷(MDA)或喷砂、浓度超过10倍允许暴露限值或职业接触限值(PEL/OEL)美国职业安全健康管理局(OSHA)特殊物质标准或适用的政府法规,以其中较低者为准,本防护口罩不产生氧气

适用行业:

适用于铸造、实验室、底漆、清洁卫生、化工农药、溶剂清洗、喷漆印刷电镀、电子业、食品加工业、汽车轮船修造、油墨染整、环境消毒等多种环境恶劣的工作场合。

说明:

此防尘口罩,用来防护非油性悬浮颗粒,过滤效率 $\geq 95\%$

能有效过滤悬浮颗粒或病菌(例如:PM2.5、SARS、禽流感、H1N1等)

★达到国标KN95标准,高滤效、低阻力

★独特加高鼻梁外观设计,可调节鼻夹,加厚海绵垫,确保密合和佩戴更舒适

★表层为PP无纺布,无毒、无味、无过敏、无刺激,透气性能佳,更适合潮湿环境使用

★选用透气性较佳的松紧织带的橡筋带,适合各种脸型使用

生产企业: 杭州生物医药国家高技术产业基地投资管理有限公司

生产地址: 浙江省杭州市钱塘新区福城路291号

电 话: 0571-86771221

营业住所: 浙江省杭州市钱塘新区白杨街道6号大街452号一幢
2A01-2A02

Manufacturer: Hangzhou Biopharmaceutical National High-tech Industrial Base Investment Management Co., Ltd.

Production address: Room 2A01-2A02, Build 1, No. 452, No. 6 Road, Baiyang Street, Qiantang District, Hangzhou City, Zhejiang Province

Phone: +86-0571-86771221



自吸过滤式防颗粒物呼吸器

产品名称: 自吸过滤式防颗粒物呼吸器

型号: 9501型

规格: 1只/袋

主要成分: 无纺布、熔喷过滤材料

生产日期: 见外箱

有效期: 一年

执行标准: GB2626-2006 KN95

储存条件: 湿度<80%, 无腐蚀性气体
和通风良好的清洁室内



HED 和达

合格证

检验员 002

使用前参见制造商提供信息

▲口罩滤料采用N95级, 过滤肉眼看不见的粉尘。

▲该口罩有效拦截、阻断、非油性颗粒物效率95%以上。

适用范围:

▲橡胶、水晶、皮毛、合成金属铸造、电池、合成化工、建材、核工、矿山、石油、造船、冶金、环卫、煤矿、油漆行业、汽车制造业等。

检查方法:

▲使用前检查口罩的包装是否破损, 原件是否正常; 如有污渍、破损, 请停止使用。在进入工作区域之前, 必须检查口罩与脸部的密合性。

如果感觉泄露, 请重新佩戴; 如没感觉泄露, 方可进入工作区工作。

注意事项:

▲当佩戴者很明显出现呼吸困难时应立即更换, 空气质量差(污染物和缺氧等)环境下, 不建议佩戴本品。

▲不能在环境温度超过50度及环境含氧量低于19.5%的情况下使用。

▲不能在有毒气体环境下使用(不能代替防毒面具), 仅适用于非油性颗粒物的呼吸防护。

▲密合框下的毛发会导致面罩泄露。

▲因为口罩存在一定的呼吸阻力, 故不建议儿童、孕妇、老人佩戴。

纵向折叠式防颗粒物口罩(耳带式)佩戴方法:



1. 面向口罩无鼻夹的一面, 两手各拉住一边耳带, 使鼻夹位于口罩上方。

2. 用口罩抵住下巴。

3. 将耳带拉至耳后, 调整耳带至感觉尽可能舒适。

4. 将双手指置于鼻夹中部, 一边向内按压一边顺着鼻夹向两侧移动指尖, 直至将鼻夹完全按压成鼻梁形状为止。仅用单手捏口罩鼻夹可能会影响口罩的密合性。

5. 在进入工作区域之前, 使用者必须检查口罩与脸部的密合性:

a) 用双手罩住口罩, 避免影响口罩在脸上的位置。

b) 如口罩无呼气阀, 快速呼气; 如口罩带呼气阀, 快速吸气。

c) 如空气从鼻梁处泄漏, 应按步骤4重新调整鼻夹; 如空气从口罩边缘泄漏, 应重新调整耳带; 如不能取得良好的密合, 应重复步骤1-4。

d) 如没有感觉泄漏, 可进入工作区工作。

生产企业: 杭州生物医药国家高技术产业基地投资管理
有限公司

生产地址: 浙江省杭州市钱塘新区福城路291号

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1幢2A01-2A02

KN95 PARTICULATE PROTECTIVE MASK

Product name: KN95 particulate protective mask
 Model: 9501
 Quantity: 1 pieces / Per bag
 Main ingredients: non-woven fabric, meltblown filter material
 Executive standard: GB2626-2006 KN95
 Production date: See packaging
 Shelf life: one year
 Recommended storage conditions: humidity <80%, non-corrosive gas and well-ventilated clean room.
 The packaging is damaged and prohibited to use. Inspectors 002
 See the manufacturer's information before use



WARNING

This respirator helps protect against certain particles. Misuse can result in sickness death. For proper use, see supervisor or User instructions on box.

Inspection Method

Before use, check whether the packaging of the mask is damaged and whether the components are normal. If there is any stain or damage, stop using it. Before entering the work area, you must check the tightness of the mask and the face. If you feel the leak, please re-wear it; if you do not feel the leak, you can enter the work area to work. (When the respiratory resistance is significantly increased or the mask does not meet the required standards, it is recommended to replace the product)

Precautions:

- This product is a self-priming filter type anti-particulate respirator
- Cannot be used when the ambient temperature exceeds 50 degrees
- Cannot be used when the ambient oxygen content is lower than 19.5%
- Cannot be used in a toxic gas environment (not a substitute for a gas mask)
- Respiratory protection for non-oily particles only
- Because the mask has some breathing resistance, it is not recommended for children, pregnant women, and the elderly

Can be used for protection

Particulate matter generated during grinding, sanding, cleaning, sawing, bagging, etc., or during the processing of ore, coal, iron ore, flour, metal, wood, pollen and some other substances, does not emit oily gas Sol or vapor liquid or non-oily particles produced by spray



Wearing Method

1. Face the face of the mask without the nose clip, and pull the ear straps with both hands so that the nose clip is above the mask.
2. Cover your chin with a mask.
3. Pull the ear strap behind your ear and adjust the ear strap to feel as comfortable as possible.
4. Place the fingers of both hands in the middle of the nose clip, press one hand inward, and move the fingertips along the nose clip to the sides until the nose clip is fully pressed into the shape of the bridge of the nose. Using only one hand to pinch the mask nose clip may affect the tightness of the mask.
5. Before entering the work area, the user must check the tightness of the mask to the face:
 - a) Cover the mask with both hands to avoid affecting the position of the mask on the face.
 - b) If the mask has no exhalation valve, exhale quickly; if the mask has an exhalation valve, inhale quickly.
 - c) If the air leaks from the bridge of the nose, readjust the nose clip according to step 4. If the air leaks from the edge of the mask, readjust the earband; if a good fit cannot be achieved, repeat steps 1-4.
 - d) If you do not feel the leak, you can enter the work area to work.

Not for protection

Gases and vapors, oily aerosols, asbestos, arsenic, cadmium, lead, 4,4'-diaminodiphenylmethane (MDA) or sandblasting at concentrations exceeding 10 times the permitted exposure limit or occupational exposure limit (PEL / OEL) US Occupational Safety and Health Administration (OSHA) special substance standards or applicable government regulations, whichever is lower, this protective mask does not generate oxygen.

Applicable industry:

Suitable for casting, laboratory, primer, cleaning and sanitation, chemical pesticide, solvent cleaning, spray printing, electroplating, electronics, food processing industry, automobile and ship building, ink dyeing and finishing, environmental disinfection

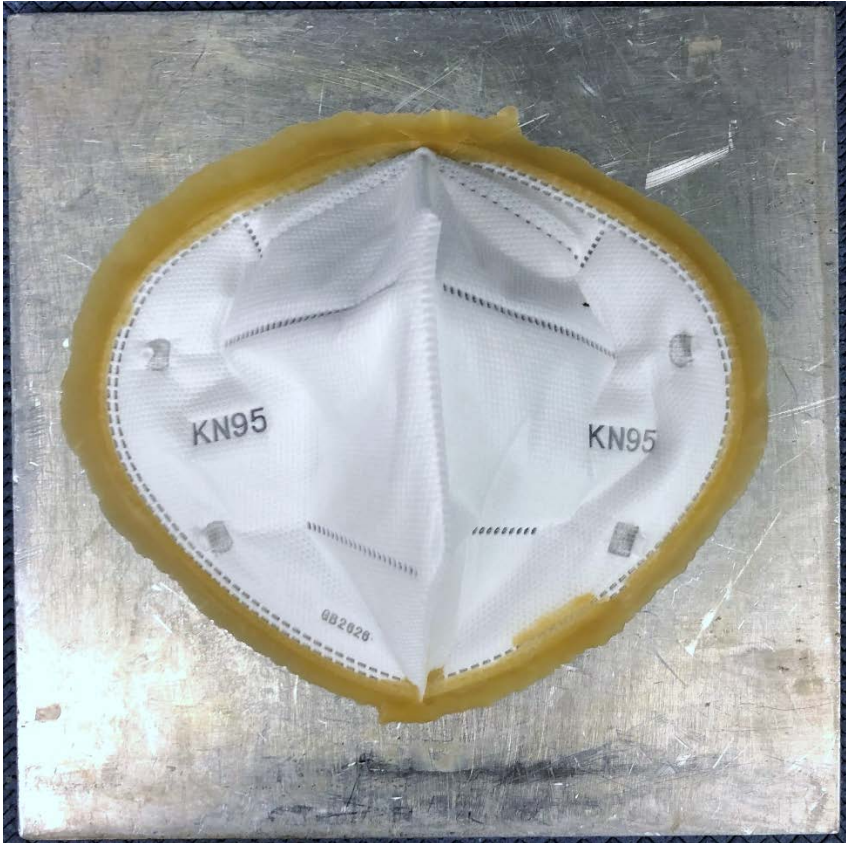
Manufacturer: Hangzhou Biopharmaceutical National High-tech Industrial Base Investment Management Co., Ltd.

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