NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Safher (Jiangsu) Medical Co., Ltd.

Model Tested: 2626-1

Date Tested: January 29, 2021

These findings pertain to the Safher (Jiangsu) Medical Co., Ltd., model 2626-1. 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 99.87% and 99.25%, respectively. All ten respirators measured more than 95% filter efficiency.

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 <u>Crisis Capacity Strategies (during known shortages)</u>.

Evaluation of International Respirators



Pictures have been added to the

end of this report.

Test: Modified TEB-APR-STP-0059

Date Tested: January 29, 2021

Report Prepared: January 29, 2021

Manufacturer: Safher (Jiangsu) Medical Co., Ltd.

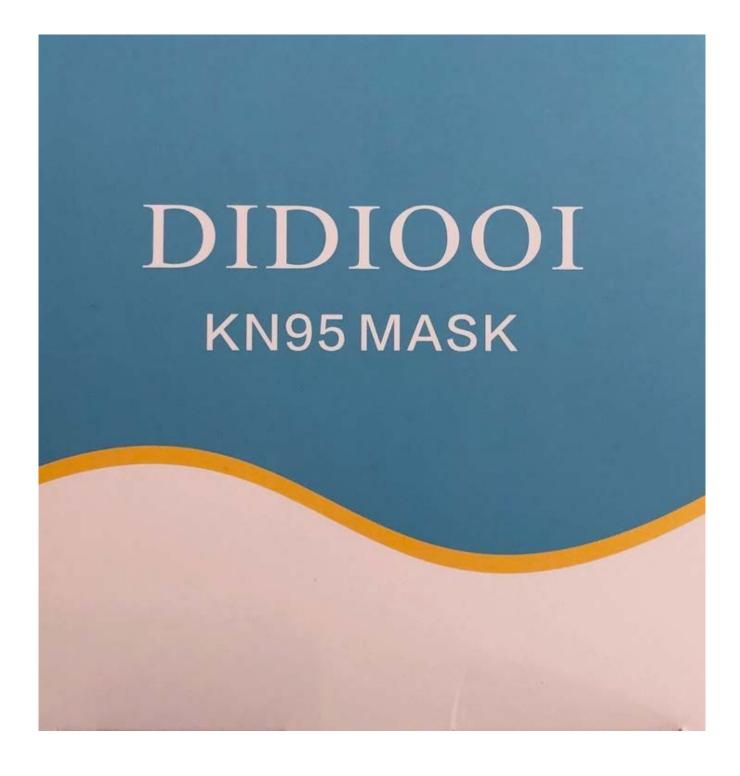
Item Tested: 2626-1

Country of Certification: China (GB2626-2006)

| Filter | Flow Rate (LPM) | Initial Filter Resistance (mmH ₂ O) | Initial Percent Leakage (%) | Maximum Percent Leakage (%) | Filter Efficiency (%) |
|--------|---------------------|--|-----------------------------------|-----------------------------|--------------------------|
| 1 | 85 | 10.3 | 0.31 | 0.33 | 99.67 |
| 2 | 85 | 11.9 | 0.44 | 0.44 | 99.56 |
| 3 | 85 | 10.6 | 0.21 | 0.21 | 99.79 |
| 4 | 85 | 11.9 | 0.31 | 0.31 | 99.69 |
| 5 | 85 | 12.0 | 0.19 | 0.19 | 99.81 |
| 6 | 85 | 11.1 | 0.40 | 0.40 | 99.60 |
| 7 | 85 | 11.7 | 0.74 | 0.75 | 99.25 |
| 8 | 85 | 11.7 | 0.17 | 0.17 | 99.83 |
| 9 | 85 | 11.1 | 0.13 | 0.13 | 99.87 |
| 10 | 85 | 12.2 | 0.15 | 0.15 | 99.85 |
| ľ | Vinimum Filter Effi | ciency: 99.25% | Maximum Filter Efficiency: 99.87% | | |

- 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.





Scope of application:

It is suitable for protection from PM2.5 haze particles, food processing, chemical industries, coal dust, cement dust, metal smelting, processing and manufacturing This product is windproof and protects againstcold.

Shelf life: 3 years

Grade: Kn95 Model: 2626-1

Standard: GB2626-2006

Storage conditions: Keep in a well-ventilated, clean room with humidity < 80%, and no corrosive gases. Application: Foldable mask(for adults)

⚠ It is very important to press the nose clip of the mask firmly against the bridge of the nose to form a good fit with the nose

Attention:

The mask should be kept as flat as possible after use, and the nose bridge at the top of the mask should not be folded frequently in order to prolong he service life.

It is not recommended to wear a mask if the airflow is not constant, or your breathing is irreguler, or you are asleep.

Not to be used forchildrenunder the age of 3,;due to their low breathing capacity:

Brand Owner: Suzhou yunyifang Information Technology Co., Ltd

Address: 7 / F, building 1, No. 888, Chenghu Road, Changqiao street, Wuzhong District, Suzhou City, Jiangsu Province, China

Manufacture: SAFHER (JIANGSU) MEDICAL CO.,LTD.

Address: No.69, Changkang Road, No.5 Bridge Industrial Park, Mashan Subdistrict, Binhu District, Wuxi, Jiangsu, China



X002IJPR23
KN95FaceMask50Pack...tration>95%SafetyMasks
New Made in China

Product Specifications:

- 1.Made from PP non-stick, non-woven fabric, a highly efficient electrostatic, electret melt- blown fabric, and an ES hot-air non-woven cotton fabric, which are used to form a high-efficiency filter layer, making it more effective at filtering aut particulates.
- 2. The 3D shape has been designed and engineered to match the shape of a human face, to ensure tightness and to increase the volume of breath while using the mask. This shape greatly improves the permeability of the mask and makes wearing and breathing more comfortable.

How to wear the mask:

- 1. Hold the side of the mask with the nose clip close to your face, with the nose clip at the top of the mask.
- 2. Put the mask against your chin with your hand.
- 3. Pull the ear straps to the back of the ears with both hands and adjust until you feel comfortable.
- 4. Place the fingers of both hands on the middle of the nose clip; press inwards while moving your fingertips along the nose clip to both sides and press the nose clip into the shape of the bridge of the nose. Pinching the nose clip with only one hand may affect the tightness of the mask.
- 5. Before entering the working area, the user must check the tightness of the mask to the face.











Made in China



产品合格证

品牌: DIDI001

品名: 日常防护口罩

型号: 2626-1

规格: 16cmX10.7cm

主要成分: 25%熔喷布, 75%无纺布

执行标准: GB2626-2006

包装规格: 50个/盒

生产批次: 20200620

生产日期: 2020年6月20日

有效期:避光干燥的室内环境下有效期3年

生产厂商: 塞弗海耳(江苏)医疗有限公司

生产地址: 中国江苏省无锡市滨湖区马山街道

五号桥工业园渔花路45号

经销商: 塞弗海耳(江苏)医疗有限公司

本产品经检验符合相关规定的质量标准

要求准予出厂





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