

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Anhui RYZUR Medical Equipment Manufacturing Co., Ltd.

Model Tested: KN95B

Date Tested: May 1, 2020

These findings pertain to the Anhui RYZUR Medical Equipment Manufacturing Co., Ltd., KN95B. The labeling and documents for this product indicate that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator) and EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

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](#).

A certificate of approval was provided with the samples received; however, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency observed was 33.90% and 27.00%, respectively. All 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 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 1, 2020

**Report Prepared:** May 3, 2020

**Manufacturer:** Anhui RYZUR Medical Equipment Manufacturing Co., Ltd.

**Item Tested:** KN95B

**Country of Certification:** China (GB2626-2006, EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	5.9	69.3	69.7	30.30
2	85	7.3	66.1	66.1	33.90
3	85	5.8	71.5	71.5	28.50
4	85	6.6	72.2	72.4	27.60
5	85	6.5	68.6	68.6	31.40
6	85	6.4	70.8	70.8	29.20
7	85	6.3	73.0	73.0	27.00
8	85	6.2	67.9	67.9	32.10
9	85	6.6	71.7	71.7	28.30
10	85	6.4	70.2	70.2	29.80
<b>Minimum Filter Efficiency: 27.00</b>			<b>Maximum Filter Efficiency: 33.90</b>		

- 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.

MTT-2020-66.3



### KN95颗粒物防护口罩

KN95 PARTICULATE RESPIRATOR MASK

1 PCS

【执行标准】GB2626-2006

【产品类型】呼吸防护用品

【产品型号】RZ95B 【防护级别】KN95

【结构组成】由口罩体、鼻梁条、口罩带组成。

【产品性能与适用范围】用于防护粉尘、烟尘、烟雾等各类颗粒状的空气污染物，对于病毒或呼吸系统疾病也有良好的呼吸防护作用。

【使用说明】打开口罩，将耳绳挂在耳朵上，调节鼻梁条，使口罩完全遮盖口鼻并贴合面部。

【注意事项】

- 1.注意产品有效期，请在有效期内使用。
- 2.不能清洗或消毒，避免重复使用,用后销毁。
- 3.包装破损，禁止使用。
- 4.对非织造布过敏者慎用。
- 5.使用前应参见使用说明。

【储存方法】存储在相对湿度不超过80%无腐蚀性气体和通风良好的室内常温保存，避免高温。

【生产日期】见合格证或外包装

【有效期】在规定的条件下储藏，有效期为3年。

【Performance Standard】GB2626-2006

【Type】Respiratory protective product

【Model】RZ95B 【Protection Grade】KN95

【Component】Mask body, nose clip and ear loops.

【Function and application】Used for protection against virus or other respiratory diseases. It can protect you from dust, droplets, saliva and bacteria.

【Instructions】Hold the mask by the ear loops. Place a loop around each ear and pinch the nose clip to the shape of your nose.

【Caution】

1. Do not use when expired.
2. Do not wash or disinfect, avoid repeated use, and destroy after use.
3. Do not use if the package is damaged.
4. Not suitable for people sensitive to non-woven fabric.
5. Please refer to the instructions before use.

【Storage】Stored at room temperature with good ventilation, non-corrosive environment and no more than 80% relative humidity. Avoid high temperature.

【Production date】See outer package or qualified certificate.

【Expiration date】36 months in the correct storage environment.

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【生产商】北京瑞山博众医疗器械有限责任公司 (A)

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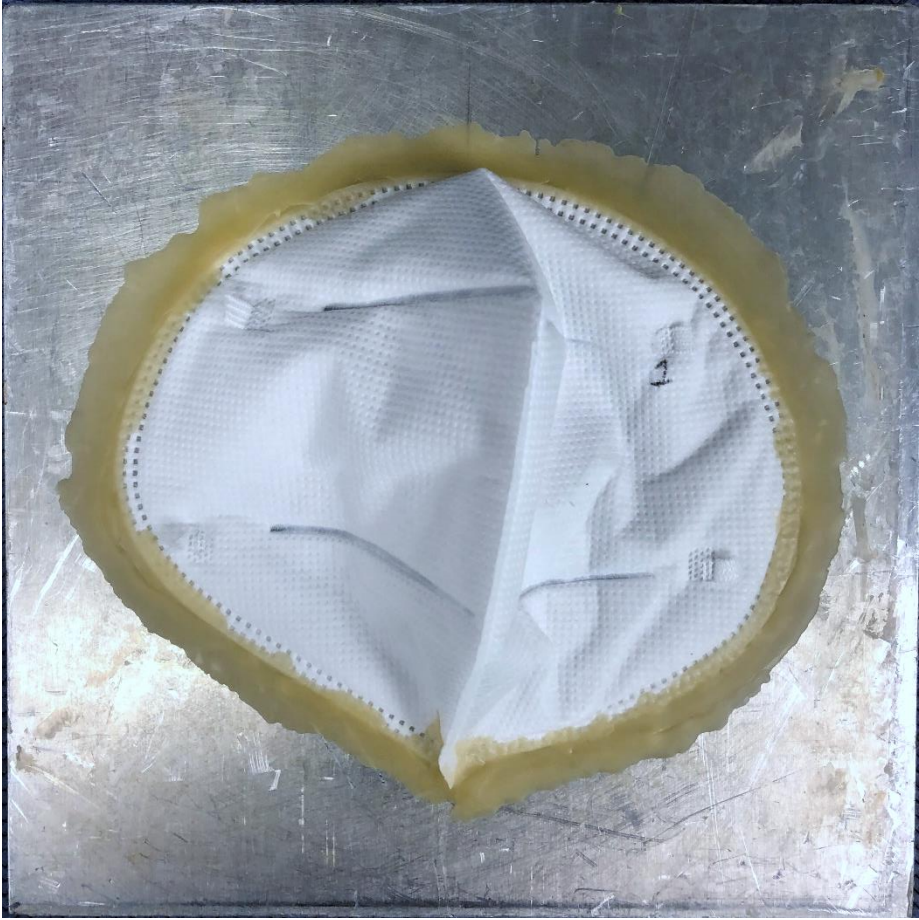
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