

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhejiang Van Beich Pharmaceutical Products Co., Ltd.

Model Tested: HB0095

Date Tested: April 15, 2021

These findings pertain to the Zhejiang Van Beich Pharmaceutical Products Co., Ltd., model HB0095. The packaging and labeling for this product indicate that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Thirty respirators were submitted for evaluation. The samples were tested using the 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 98.72% and 79.04%, respectively. Seven respirators measured more than 95% filtration efficiency. Twenty-three measured less than 95% filtration 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 [Crisis Capacity Strategies \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: April 15, 2021

Report Prepared: April 16, 2021

Manufacturer: Zhejiang Van Beich Pharmaceutical Products Co., Ltd.

Item Tested: HB0095

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	10.9	3.12	3.56	96.44
2	85	10.8	1.25	1.34	98.66
3	85	29.6	5.97	5.97	94.03
4	85	10.3	1.64	1.75	98.25
5	85	10.5	1.24	1.28	98.72
6	85	13.3	3.21	3.21	96.79
7	85	12.1	1.77	1.84	98.16
8	85	33.2	5.62	5.62	94.38
9	85	29.6	6.34	6.34	93.66
10	85	27.7	6.74	6.74	93.26
Minimum Filter Efficiency: 93.26%			Maximum Filter Efficiency: 98.72%		

- 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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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
11	85	11.0	3.52	3.62	96.38
12	85	30.6	8.97	8.97	91.03
13	85	28.6	6.34	6.34	93.66
14	85	25.4	6.32	6.32	93.68
15	85	29.2	7.36	7.36	92.64
16	85	26.5	16.15	16.15	83.85
17	85	28.8	14.55	14.55	85.45
18	85	33.7	17.61	17.61	82.39
19	85	27.4	13.70	13.70	86.30
20	85	30.0	12.23	12.23	87.77
Minimum Filter Efficiency: 82.39%			Maximum Filter Efficiency: 96.38%		

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21	85	32.9	20.96	20.96	79.04
22	85	34.0	13.99	13.99	86.01
23	85	30.8	11.74	11.74	88.26
24	85	31.6	12.55	12.55	87.45
25	85	31.9	11.78	11.78	88.22
26	85	37.4	17.41	17.41	82.59
27	85	36.4	14.67	14.67	85.33
28	85	37.2	12.66	12.66	87.34
29	85	33.8	11.15	11.15	88.85
30	85	39.3	12.29	12.29	87.71
Minimum Filter Efficiency: 79.04%			Maximum Filter Efficiency: 88.85%		

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合格证 Product certification

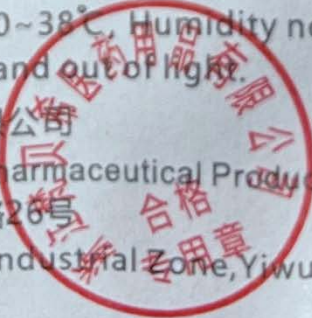
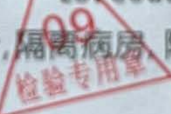
产品名称: 随弃式面罩KN95(非医用) 检验员: 09
Product : Disposable face Mask KN95 (non-medical) Tester : 09
产品型号: HB0095 执行标准: GB2626-2006
Product Model : HB0095 Executive Standard: GB2626-2006
主要材料: 无纺布40%熔喷布30% 生产日期: 见外包装
Material : Non-Woven Fabric 40% Mfg Date: Look at the outer packing
Melt-blown Nonwovens 30% 截止日期: 见外包装
Hot air cotton 30% Exp Date: Look at the outer packing
生产批号: 见外包装
Lot Code: Look at the outer packing

使用禁忌: 本产品不得用于发热门诊, 隔离病房, 隔离留观病房, 手术室, 隔离重症监护室等区域。

Forbidden: This product cannot be used in these areas such as fever clinic, isolation wards, operating room, ICU, etc.

储存条件: 储存温度-20~38°C, 储存湿度<80%, 避光干燥的室内。
Storage: Temperature between -20~38°C, Humidity not exceed 80%. Store in dry room and out of light.

生产企业: 浙江梵贝希医药用品有限公司
Productor : Zhejiang Van Beich Pharmaceutical Products Co., Ltd
生产地址: 义乌市义南工业区大士路26号
Address: 26 Dashi Road, Yinan Industrial Zone, Yiwu City
联系电话: 0579-89982605
Tel: (86)-579-8998 2605



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