NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Chengde Technology Co., Ltd. Model Tested: KN95 Folding Protective Mask

Date Tested: October 23, 2020

These findings pertain to the Chengde Technology Co., Ltd., model KN95 Folding Protective Mask. 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 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 99.95% and 98.83%, respectively. All thirty respirators measured more 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 <u>Crisis Capacity Strategies (during known shortages)</u>.

Evaluation of International Respirators



Test: Modified TEB-APR-STP-0059

Date Tested: October 23, 2020

Report Prepared: October 23, 2020

Manufacturer: Chengde Technology Co., Ltd. **Item Tested:** KN95 Folding 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 (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	11.5	0.85	0.85	99.15
2	85	19.6	0.09	0.09	99.91
3	85	17.9	0.07	0.07	99.93
4	85	21.7	0.08	0.08	99.92
5	85	14.0	1.12	1.12	98.88
6	85	17.8	0.09	0.09	99.91
7	85	24.5	0.08	0.08	99.92
8	85	19.9	0.19	0.19	99.81
9	85	20.0	0.10	0.10	99.90
10	85	19.6	0.06	0.06	99.94
N	Vinimum Filter Effi	ciency: 98.88%	Maximum Filter Efficiency: 99.94%		

- 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.

Evaluation of International Respirators



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end of this report.

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Report Prepared: October 23, 2020

Manufacturer: Chengde Technology Co., Ltd.

Item Tested: KN95 Folding Protective Mask

Country of Certification: China (GB2626-2006)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)	
11	85	20.3	0.05	0.05	99.95	
12	85	18.2	0.13	0.13	99.87	
13	85	28.8	0.10	0.10	99.90	
14	85	21.8	0.07	0.07	99.93	
15	85	17.1	0.05	0.05	99.95	
16	85	20.6	0.13	0.13	99.87	
17	85	20.4	0.07	0.07	99.93	
18	85	16.5	0.05	0.05	99.95	
19	85	23.9	0.16	0.16	99.84	
20	85	25.0	0.17	0.17	99.83	
N	Minimum Filter Efficiency: 99.83%			Maximum Filter Efficiency: 99.95%		

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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
21	85	19.0	0.09	0.09	99.91
22	85	19.5	0.12	0.12	99.88
23	85	14.4	1.17	1.17	98.83
24	85	12.9	0.97	0.97	99.03
25	85	27.9	0.13	0.13	99.87
26	85	21.2	0.10	0.10	99.90
27	85	20.1	0.13	0.13	99.87
28	85	26.1	0.08	0.08	99.92
29	85	11.8	0.80	0.80	99.20
30	85	23.9	0.16	0.16	99.84
Minimum Filter Efficiency: 98.83%			Maximum Filter Efficiency: 99.92%		

- 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.
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CERTIFICATE OF CONFORMITY 产品名称: KN95折叠式防护口罩 Product name: KN95 Folding Protective Mask 执行标准: GB2626-2006 Executive Standard: GB2626-2006 牌: CHENODE Brand: 产品规格: 160*105mm Product specification: 160*105mm 主要原料:51% 无纺布+29%熔喷布+20%热风棉 Main Material: 51% Non Woven+29% Meltblown+20% Hot air cotton 产品批号: 见包装袋 产品颜色: 白色 Batch No: See packing bag Colors: White 检验日期、见包装袋 生产日期: 见包装袋 Production Date: See packing bag Inspection date: See packing bag 有效期: 3年 使用周期:一次性 Shelf life 2 years Use cycle: disposable 产品型号: CD9501B Product Type: Type CD9501B 生产企业: 诚德科技股份有限公司 Manufacturer: Chengde Technology Co., Ltd 生产地址: 浙江省龙港市世纪大道888-1088号 Add: No. 888 - 1088 Shiji Ave, Longgang City, Zhejiang Province 联系电话: 057759889395 Tel: 86 577 59889395 产品使用范围:本产品不得用于发热门诊隔离病房(区) 隔离留观病房(区)手术室、隔离重症监护室等区域。 product range of use: This product should not be used in the area of isolated wards for fever diagnosis, isolated observation wards, operating rooms, isolated wards, etc. 本产品为非医疗器械 THIS PRODUCT IS A NON-MEDICAL DEVICE MADE IN CHINA





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