NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Jinhua Jiadaifu Medical Supplies Co., Ltd.

Model Tested: KN95 Mask Date Tested: January 19, 2021

These findings pertain to the Jinhua Jiadaifu Medical Supplies Co., Ltd., model KN95 Mask. The packaging for this product indicates 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 respirators were sampled into groups of ten 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 99.83% and 98.86%, 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



Pictures have been added to the

end of this report.

Test: Modified TEB-APR-STP-0059

Date Tested: January 19, 2021

Report Prepared: January 19, 2021

Manufacturer: Jinhua Jiadaifu Medical Supplies Co., Ltd.

Item Tested: KN95 Mask

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	12.7	0.21	0.21	99.79	
2	85	15.5	1.14	1.14	98.86	
3	85	12.6	0.50	0.50	99.50	
4	85	13.0	0.33	0.34	99.66	
5	85	14.1	0.31	0.31	99.69	
6	85	12.9	0.33	0.33	99.67	
7	85	12.8	0.25	0.25	99.75	
8	85	15.5	0.36	0.36	99.64	
9	85	12.3	0.30	0.30	99.70	
10	85	11.8	0.23	0.23	99.77	
ſ	Minimum Filter Efficiency: 98.86%			Maximum Filter Efficiency: 99.79%		

- 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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Item Tested: KN95 Mask

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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 (%)
11	85	17.2	0.23	0.23	99.77
12	85	13.3	0.17	0.17	99.83
13	85	13.0	0.35	0.35	99.65
14	85	14.7	0.28	0.28	99.72
15	85	14.8	0.31	0.31	99.69
16	85	11.9	0.41	0.41	99.59
17	85	12.7	0.27	0.27	99.73
18	85	12.7	0.34	0.34	99.66
19	85	12.3	0.25	0.25	99.75
20	85	11.4	0.37	0.37	99.63
	Minimum Filter Efficiency: 99.59%		Maximum Filter Efficiency: 99.83%		

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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
21	85	13.7	0.36	0.36	99.64
22	85	18.3	0.19	0.19	99.81
23	85	17.2	0.44	0.44	99.56
24	85	14.9	0.30	0.30	99.70
25	85	14.4	0.44	0.44	99.56
26	85	11.5	1.09	1.10	98.90
27	85	10.4	0.71	0.71	99.29
28	85	14.9	0.42	0.42	99.58
29	85	13.8	0.55	0.55	99.45
30	85	14.5	0.42	0.42	99.58
Minimum Filter Efficiency: 98.91%		Maximum Filter Efficiency: 99.81%			

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INSTRUCTION FOR USE:

- 1.Failure to follow all instructions and limitations on the use of this respirator and /or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and result in sickness or death.
- in sickness or death.
 2.Before use, wearer must first be trained by the employer for proper respirator use in accordance with applicable Safety and Health Standards. Respiratory protection appliances are to be selected depending on the type and concentration of the hazardous.
 3.Do not use the protection against, Vapor in atmospheres containing less tha 17% Oxygen.
- 4.The respirator may only be used if the type and concentration of the harmful substances are known. In case of unknown substances or concentrations or variable conditions, breathing apparatus should be used.
- 5.Non-ventilated containers, mines, canals should not be entered with the particle filtering half masks & also not allowed in explosive atmosphere.
- 6.If the respirator becomes damaged or breathing becomes difficult, leave the contaminated area, discard and replace the respirator. Also leave the contaminated area immediately if dizziness or other distress occurs
- 7. Never alter or modify this respirator.
- 8.Do not use with beard or other facial hair that prevent direct contact betweenthe face and the edge of the respirator.
- 9.Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown, or when particulate concentration exceed the maximum use levels /or other levels deter mined by your national Occupational Safety and Health authorities.
- 10.Particular attention should be paid to the rules regarding the use of breath –protection apparatus (BGR190/ZH1/701) and the industrial safety principles for occupational medicine precaution tests G26 or applicable National Occupational Safety & Health rules.

USAGE LIFE:

Mask gets clogged with dust particles indicated by increase in breathing resistance. The filter respirator is meant foe single person use. The duratio of use should be maximum single shift.

STORAGE INSTRUCTIONS:

The filter respirator until use shall be stored in the pack to retain its properties. For transport such Packs shall—be suitably packed in outer cartons to protect from climatic hazards and mechanical shocks.















产品合格证 PRODUCT CERTIFICATE

产品名称 Product Name	非医用随弃式口罩(KN95) Disposable Non-medical Face Mask (KN95)	
产品规格 Product specification	160mm*105mm	
执行标准 Executive Standard	GB2626-2006	
产品性能 Product performance	PFE≥95%,达到KN95级别 PFE≥95%, reach KN95 level	
主要成分 Main ingredients	无纺布40%、熔喷布30%、热风棉30% Non-woven fabric40%, Melt blown fabric30%, Hot air cotton30%	
包装规格 Packing	5片/包 5 pcs/bag レキ医护田 ロメ	
生产日期 Production Date	20200810	
生产批号 Batch No	K20200810	
使用期限 Expiration Date	所 2 years (2)	
检验员 Inspector	02	
生产企业 Manufacture	金华家大夫医护用品有限公司 Jinhua Jiadaifu Medical Supplies co., LTD.	
生产地址 Address	中国浙江省金华市婺城区白龙桥镇洞溪工业区 Dongxi industrial zone, Bailongqiao Town, Wucheng District, Jinhua City, Zhejiang Province, China	
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MADE IN CHINA





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