

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Tianjin Benmo Medical Equipment Co., Ltd.

Model Tested: KN95

Date Tested: June 20, 2020

These findings pertain to the Tianjin Benmo Medical Equipment Co., Ltd., model KN95. 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 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 99.61% and 93.07%, respectively. Twenty-nine respirators measured more than 95%. One respirator measured less than 95%. (Note: The test technician noted that the material was very thin around the area where the strap attaches.)

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: June 20, 2020

Report Prepared: June 20, 2020

Manufacturer: Tianjin Benmo Medical Equipment Co., Ltd.

Item Tested: KN95 (Sample Group 1 of 3)

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	8.4	2.80	2.81	97.19
2	85	7.9	2.96	2.97	97.03
3	85	22.0	0.65	0.65	99.35
4	85	19.9	1.21	1.21	98.79
5	85	7.9	1.95	1.97	98.03
6	85	8.5	2.20	2.20	97.80
7	85	22.9	0.60	0.60	99.40
8	85	10.4	2.08	2.08	97.92
9	85	27.1	6.93	6.93	93.07
10	85	23.7	2.68	2.68	97.32
Minimum Filter Efficiency: 93.07			Maximum Filter Efficiency: 99.40		

- 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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Test: Modified TEB-APR-STP-0059

Date Tested: June 20, 2020

Report Prepared: June 20, 2020

Manufacturer: Tianjin Benmo Medical Equipment Co., Ltd.

Item Tested: KN95 (Sample Group 2 of 3)

Country of Certification: China (GB2626-2006)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	21.1	1.36	1.36	98.64
12	85	9.8	2.65	2.75	97.25
13	85	8.4	1.81	1.82	98.18
14	85	9.1	1.96	2.11	97.89
15	85	12.0	0.46	0.46	99.54
16	85	21.0	2.66	2.66	97.34
17	85	20.4	0.71	0.71	99.29
18	85	18.8	0.86	0.86	99.14
19	85	18.8	1.78	1.78	98.22
20	85	20.5	1.28	1.28	98.72
Minimum Filter Efficiency: 97.25			Maximum Filter Efficiency: 99.54		

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Test: Modified TEB-APR-STP-0059

Date Tested: June 20, 2020

Report Prepared: June 20, 2020

Manufacturer: Tianjin Benmo Medical Equipment Co., Ltd.

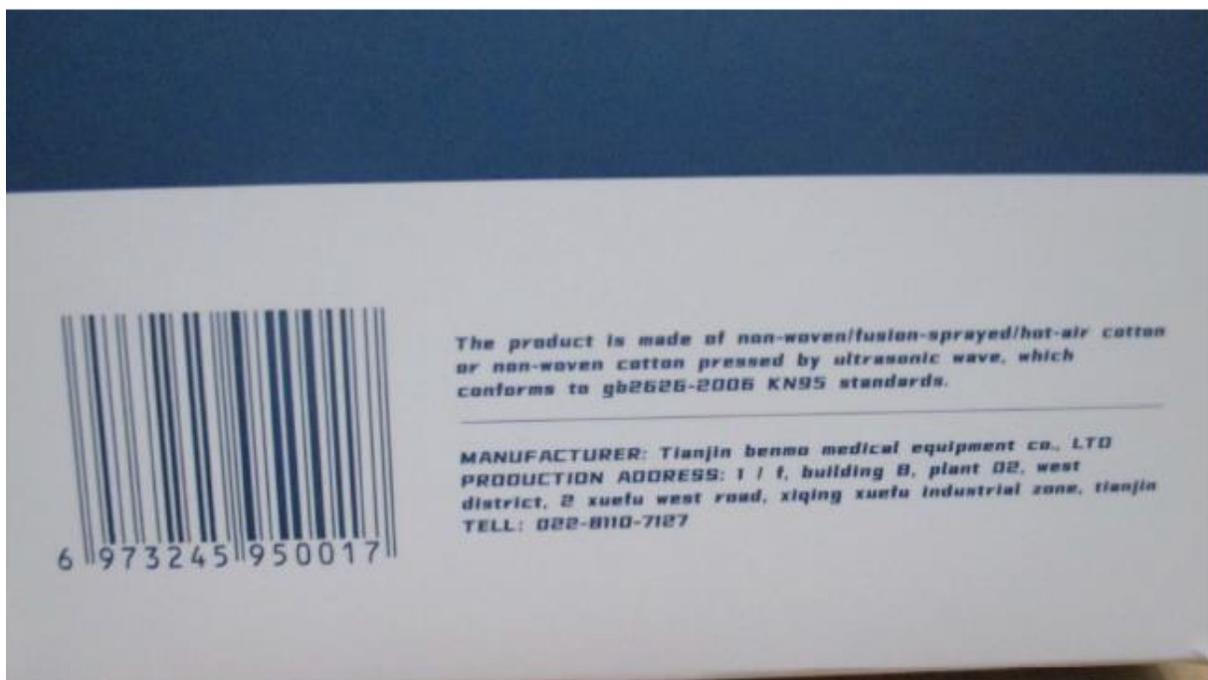
Item Tested: KN95 (Sample Group 3 of 3)

Country of Certification: China (GB2626-2006)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
21	85	8.1	2.24	2.32	97.68
22	85	31.6	4.36	4.36	95.64
23	85	14.6	0.39	0.39	99.61
24	85	13.1	0.54	0.54	99.46
25	85	19.7	2.73	2.73	97.27
26	85	20.0	2.09	2.09	97.91
27	85	19.0	2.41	2.41	97.59
28	85	18.8	1.99	1.99	98.01
29	85	16.8	4.62	4.62	95.38
30	85	16.1	3.90	3.90	96.10
Minimum Filter Efficiency: 95.38			Maximum Filter Efficiency: 99.61		

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DND® **PROTECTIVE MASKS** 

合格证 Certificate Of Conformity

产品名:	DND牌KN95型折叠式防护口罩
Name:	DND KN95 Folding protective mask
产品型号:	KN95
Model:	
品牌:	DND
Brand:	
规格:	165x100mm
Specification:	
材质:	41.3%无纺布 21.7%熔喷布 37%无纺棉
Materials:	41.3% non-woven fabrics, 21.7% melt-blown fabrics, 37% non-woven cotton
数量:	2只
Number:	2 pieces
执行标准:	GB 2626-2006
Standards:	
适用范围:	适用于各类颗粒物环境下, 过滤空气中的各类颗粒物
Intended Use:	It is suitable for filtering all kinds of particles in the air under the environment of all kinds of particles
生产日期:	2020年5月15日
Manufacturing Date:	15 May 2020
生产批次:	020515
Production Batch No.:	
有效期:	储存温度-20~50℃, 储存湿度≤80%, 避光干燥的室内环境下, 有效期3年。
Shelf Life:	three years if stored in dry environment at room temperature -20-50 °C and humidity ≤ 80%
生产企业:	天津本末医疗器械有限公司
Producer:	Tianjin Benmo Medical Equipment Co., Ltd.
生产地址:	天津市西青学府工业园学府西路2号西区D2号厂房B座1层
Production Address:	D2-B1, West Area, No.2, West Xuefu Road, Xuefu Industrial Park, Xiqing District, Tianjin.

天津本末医疗器械有限公司
合格品检验专用

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