

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guizhou Bocai Medical Equipment Co. Ltd.

Model Tested: KN95 Non-Medical Respiratory Protective Mask

Date Tested: July 23, 2020

These findings pertain to the Guizhou Bocai Medical Equipment Co. Ltd., model KN95 Non-Medical Respiratory Protective 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 98.52% and 90.22%, respectively. Eighteen respirators measured more than 95%. Twelve 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 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: July 23, 2020

Report Prepared: July 23, 2020

Manufacturer: Guizhou Bocai Medical Equipment Co. Ltd.

Item Tested: KN95 Non-Medical Respiratory Protective Mask (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	16.7	3.99	4.12	95.88
2	85	15.5	1.99	2.02	97.98
3	85	12.7	2.31	2.31	97.69
4	85	14.7	2.67	2.67	97.33
5	85	18.5	2.10	2.10	97.90
6	85	18.0	3.96	3.96	96.04
7	85	14.7	1.95	1.95	98.05
8	85	14.7	7.62	8.79	91.21
9	85	14.3	2.14	2.14	97.86
10	85	17.1	4.28	4.28	95.72
Minimum Filter Efficiency: 91.21			Maximum Filter Efficiency: 98.05		

- 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.

NPPTL COVID-19 Response: International Respirator Assessment

Test: Modified TEB-APR-STP-0059

Date Tested: July 23, 2020

Report Prepared: July 23, 2020

Manufacturer: Guizhou Bocai Medical Equipment Co. Ltd.

Item Tested: KN95 Non-Medical Respiratory Protective Mask (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	14.2	2.07	2.07	97.93
12	85	14.9	5.32	6.62	93.38
13	85	16.0	3.58	3.64	96.36
14	85	13.5	4.66	4.87	95.13
15	85	17.9	8.51	9.66	90.34
16	85	19.4	7.01	7.66	92.34
17	85	14.6	7.74	8.03	91.97
18	85	16.1	9.51	9.78	90.22
19	85	16.2	6.33	6.43	93.57
20	85	14.8	2.78	2.78	97.22
Minimum Filter Efficiency: 90.22			Maximum Filter Efficiency: 97.93		

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NPPTL COVID-19 Response: International Respirator Assessment

Test: Modified TEB-APR-STP-0059

Date Tested: July 23, 2020

Report Prepared: July 23, 2020

Manufacturer: Guizhou Bocai Medical Equipment Co. Ltd.

Item Tested: KN95 Non-Medical Respiratory Protective Mask (Sample Group 3 of 3)

Country of Certification: China (GB2626-2006)

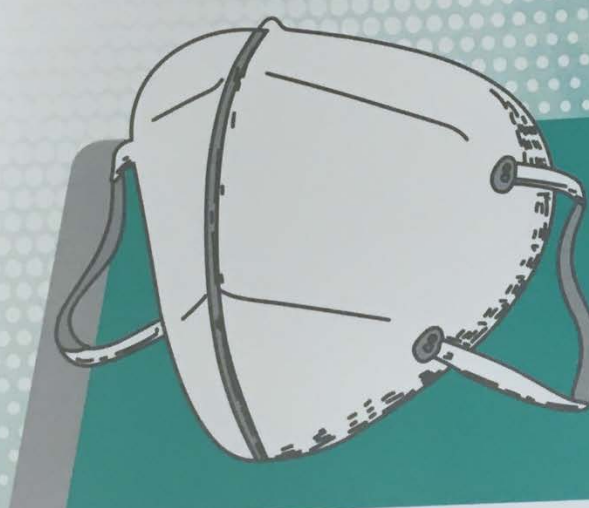
Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
21	85	13.4	5.28	5.60	94.40
22	85	15.9	1.75	1.75	98.25
23	85	13.3	8.45	9.22	90.78
24	85	11.2	2.81	2.81	97.19
25	85	16.0	3.12	3.16	96.84
26	85	15.7	7.24	7.48	92.52
27	85	14.3	3.06	3.06	96.94
28	85	17.2	8.05	8.77	91.23
29	85	25.1	1.48	1.48	98.52
30	85	15.1	5.83	6.24	93.76
Minimum Filter Efficiency: 90.78			Maximum Filter Efficiency: 98.52		

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KN95 Non Medical RESPIRATORY PROTECTIVE MASK

Ear loop Type mask PFE ≥ 95%

Made in China / GB2626-2006




- Bacterial filtration
- High filtration
- Comfortable skin
- Harmful material protection

20 PCS

FIVE-LAYER FILTER MORE SECURITY
CAN EFFECTIVELY FILTER DUST HAZE
贵州博材医疗器械有限公司

SCOPE OF USE



The respirator can be used for respiratory protection of some non oily particles, such as dust, sand dust, pollen, influenza virus and other pathogenic microorganisms, all kinds of productive dust and non-volatile fog and other air pollutants. It can be used as the protection of PM2.5

[Product name] Non medical respiratory protective
[Main ingredients] skin friendly non-woven layer, hot air cotton, antibacterial non-woven fabric, melt blown fabric, non-woven fabric
[Main raw materials] non-woven 46.57% + melt blown 28.58% + hot air cotton 24.85%
[Product performance] PFE ≥ 95%
[Normal color] white
[Product size] 10*15.5cm (±0.3)
[Package] 20 pcs
[Validity period] three years
[Executive standard] GB2626-2006 kn95
生产企业: 贵州博材医疗器械有限公司
[Manufacturer] Guizhou Bocai Medical Equipment Co., Ltd
生产地址: 中国-贵州省遵义市红花岗区深溪健康医药产业园
[Address] Honghuagang District, Zunyi City, Guizhou Province, China

BAT.: 20200502
3020/05/04
MAN.:

See the certificate of conformity in the box

BOCAI 博材™



合格证 CERTIFICATION

Kn95拱形防护口罩 Kn95 Respiratory Protective Mask

产品尺寸 / 数量: 10*15.5cm(±0.3) / 20只装

Product Size: 10*15.5cm(±0.3) / Package: 20pcs/box

产品颜色: 白色

Product Color: White

执行标准: GB2626-2006

Executive standard: GB2626-2006

产品性能: PFE ≥ 95%

Product performance: PFE ≥ 95%

原材料: 无纺布46.57%, 熔喷布28.58%, 热风棉24.85%

Raw materials: 46.57% non-woven, 28.58% melt blown, 24.85% Hot air cotton

生产批号 / production batch: K20200502

生产日期 / Production Date: 2020/05/04

有效期 / Shelf Life: 3 years

检验员 / Inspectors: BC-01 BC-02

生产企业: 贵州博材医疗器械有限公司

Manufacturer: Guizhou Bocai Medical Equipment Co., Ltd.

电话 / Tel:

生产地址: 中国·贵州省遵义市红花岗区深溪健康医药产业园

Address: Honghuagang District, Zunyi City, Guizhou

Privubce, China



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