

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhejiang Shaohua Medical Equipment Co., Ltd.

Model Tested: 3D protective mask

Date Tested: June 1, 2021

These findings pertain to the Zhejiang Shaohua Medical Equipment Co., Ltd., model 3D 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). The packaging also indicates that this product meets EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

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 99.81% and 97.09%, respectively. All thirty respirators measured more than 95% filter 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: June 1, 2021

Report Prepared: June 1, 2021

Manufacturer: Zhejiang Shaohua Medical Equipment Co., Ltd.

Item Tested: 3D Protective Mask

Country of Certification: China (GB2626-2006), European (EN149:2001+A1:2009)

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	16.2	0.50	0.50	99.50
2	85	17.0	0.29	0.29	99.71
3	85	13.0	1.62	1.62	98.38
4	85	16.7	0.34	0.34	99.66
5	85	15.6	0.29	0.29	99.71
6	85	20.6	1.75	1.75	98.25
7	85	18.6	0.55	0.55	99.45
8	85	18.3	0.23	0.23	99.77
9	85	12.7	1.27	1.27	98.73
10	85	13.2	0.93	0.93	99.07
Minimum Filter Efficiency: 98.25%			Maximum Filter Efficiency: 99.77%		

- 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	20.4	0.22	0.22	99.78
12	85	17.1	0.40	0.40	99.60
13	85	17.6	0.27	0.27	99.73
14	85	18.0	0.40	0.40	99.60
15	85	18.5	0.34	0.34	99.66
16	85	21.4	0.45	0.45	99.55
17	85	19.0	0.25	0.25	99.75
18	85	19.8	0.21	0.21	99.79
19	85	15.1	1.45	1.45	98.55
20	85	16.0	1.67	1.67	98.33
Minimum Filter Efficiency: 98.33%			Maximum Filter Efficiency: 99.79%		

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21	85	14.4	1.29	1.29	98.71
22	85	20.0	0.19	0.19	99.81
23	85	17.5	0.37	0.37	99.63
24	85	16.7	0.41	0.41	99.59
25	85	18.2	2.68	2.91	97.09
26	85	18.7	0.26	0.26	99.74
27	85	16.8	1.46	1.47	98.53
28	85	21.8	0.22	0.22	99.78
29	85	15.7	1.17	1.17	98.83
30	85	16.0	0.57	0.57	99.43
Minimum Filter Efficiency: 97.09%			Maximum Filter Efficiency: 99.81%		

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KN95

Protective Respirator Mask

ER-PRO™

Protective Gear for Professionals



Protect Against:

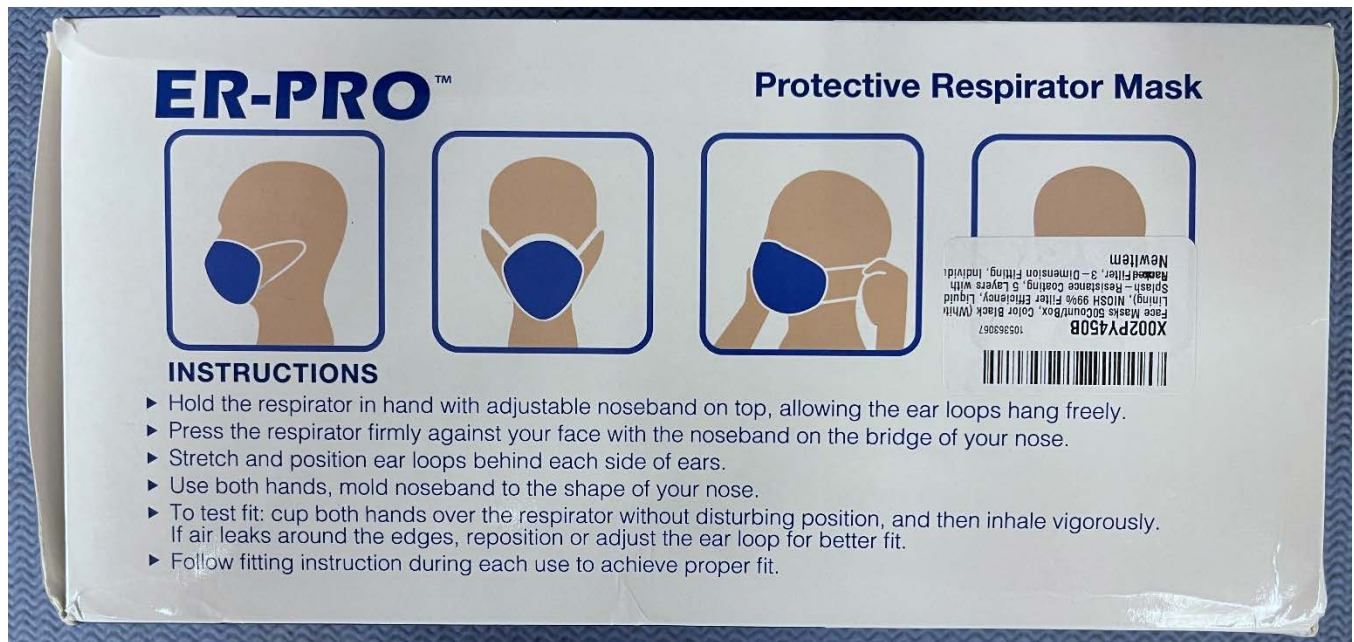
Droplets
Dust & Fog
Liquid Splash
PM2.5 Particles

50 PACKS

Individually Sealed

3-Dimensional Fit • 4-Layer with Nano-Fiber Filter • Adjustable Noseband • Latex Free

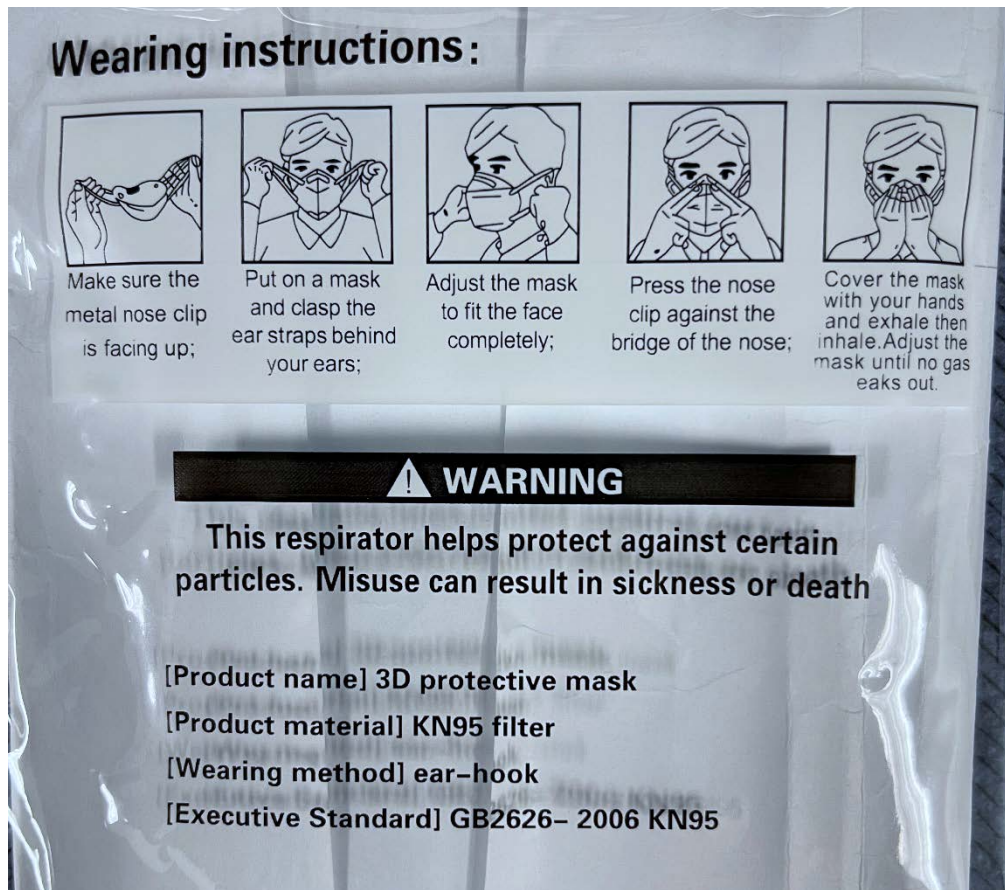
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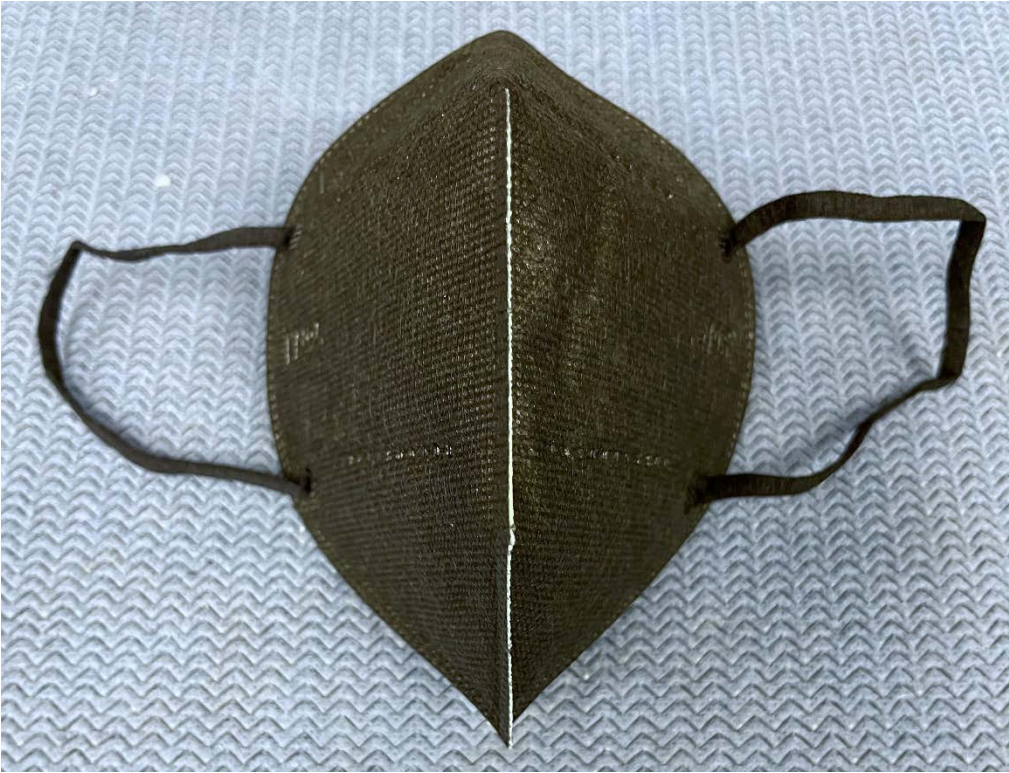
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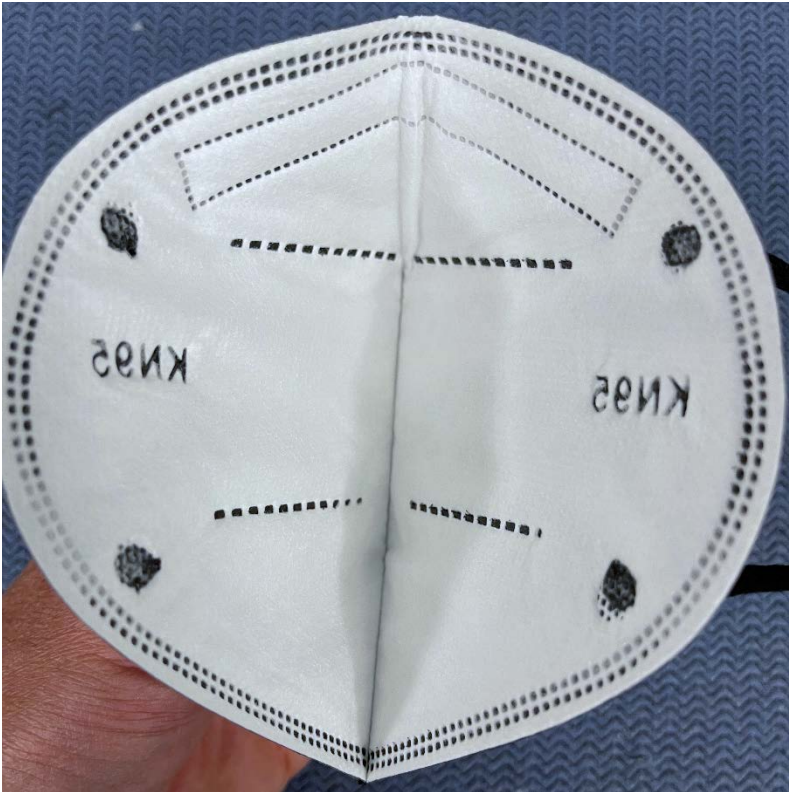
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