NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhangjiagang Zhiyi Medical Health Products Co., Ltd.
Model Tested: Self-Priming Filter Respirator KN95
Date Tested: April 10, 2020

These findings pertain to the Zhangjiagang Zhiyi Medical Health Products Co., Ltd., KN95 Self-Priming Filter Respirator. The labeling for these respirators indicate they meet GB19083-2010. This is the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

Ten 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.

The maximum and minimum filter efficiency of the products evaluated was 99.26% and 97.93%, respectively. All ten respirators measured more than 95%.

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. Therefore, even though the filter efficiency measured was more than 95%, users need to ensure a proper fit is achieved.

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.

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

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: April 10, 2020

Report Prepared: April 15, 2020

Pictures have been added to the end of this report.

Manufacturer: Zhangjiagang Zhiyi Medical Health Products Co., Ltd.

Item Tested: Self-Priming Filter Respirator KN95

Country of Certification: China (GB19083-2010)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	9.5	0.736	0.736	99.26
2	85	8.2	2.07	2.07	97.93
3	85	9.3	0.831	0.831	99.17
4	85	10.0	1.46	1.46	98.54
5	85	10.2	1.31	1.31	98.69
6	85	9.3	0.849	0.849	99.15
7	85	9.4	0.943	0.943	99.06
8	85	8.9	0.765	0.765	99.23
9	85	8.6	1.09	1.09	98.91
10	85	9.8	1.24	1.24	98.76
Minimum Filter Efficiency: 97.93			**Maximum Filter Efficiency: 99.26**		

- 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.


SELF-PRIMING FILTER
RESPIRATOR
自吸过滤式防颗粒呼吸器
ZHIYI
KN95
SELF-PRIMING FILTER
RESPIRATOR
自吸过滤式防颗粒呼吸器
KN95
50
使用须知
应用范围：


20200316
2020-03-16
2023-03-15

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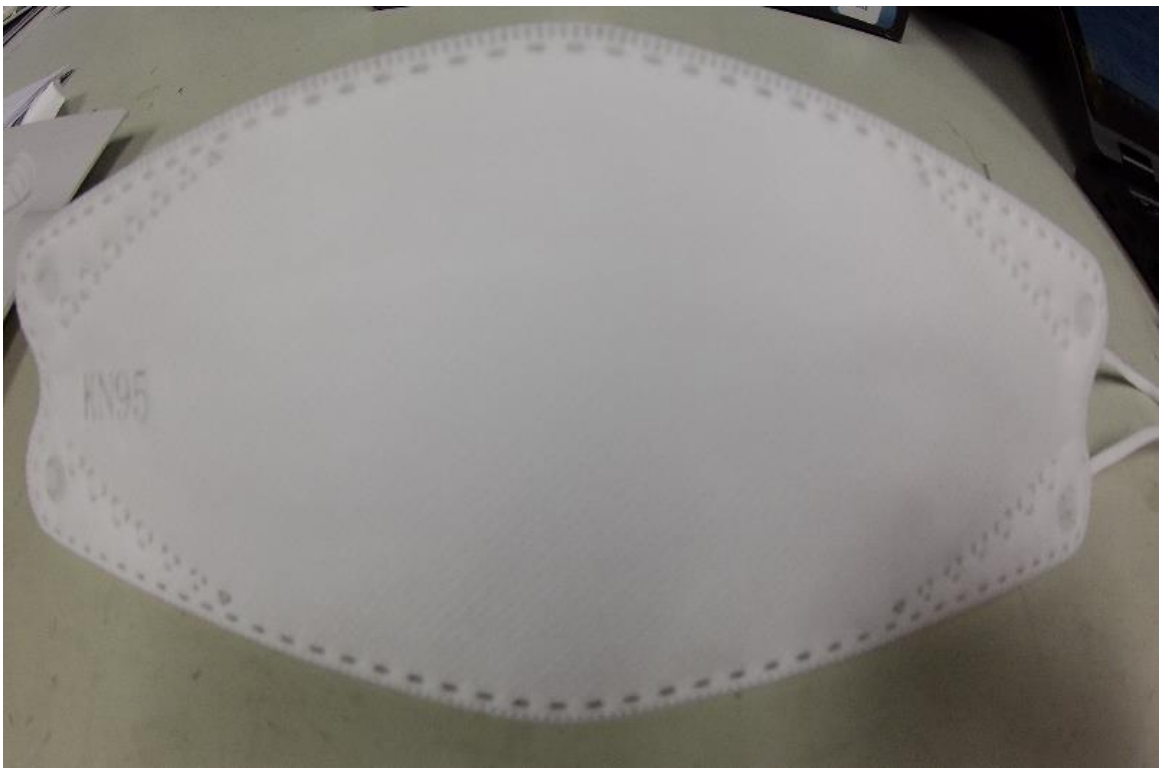

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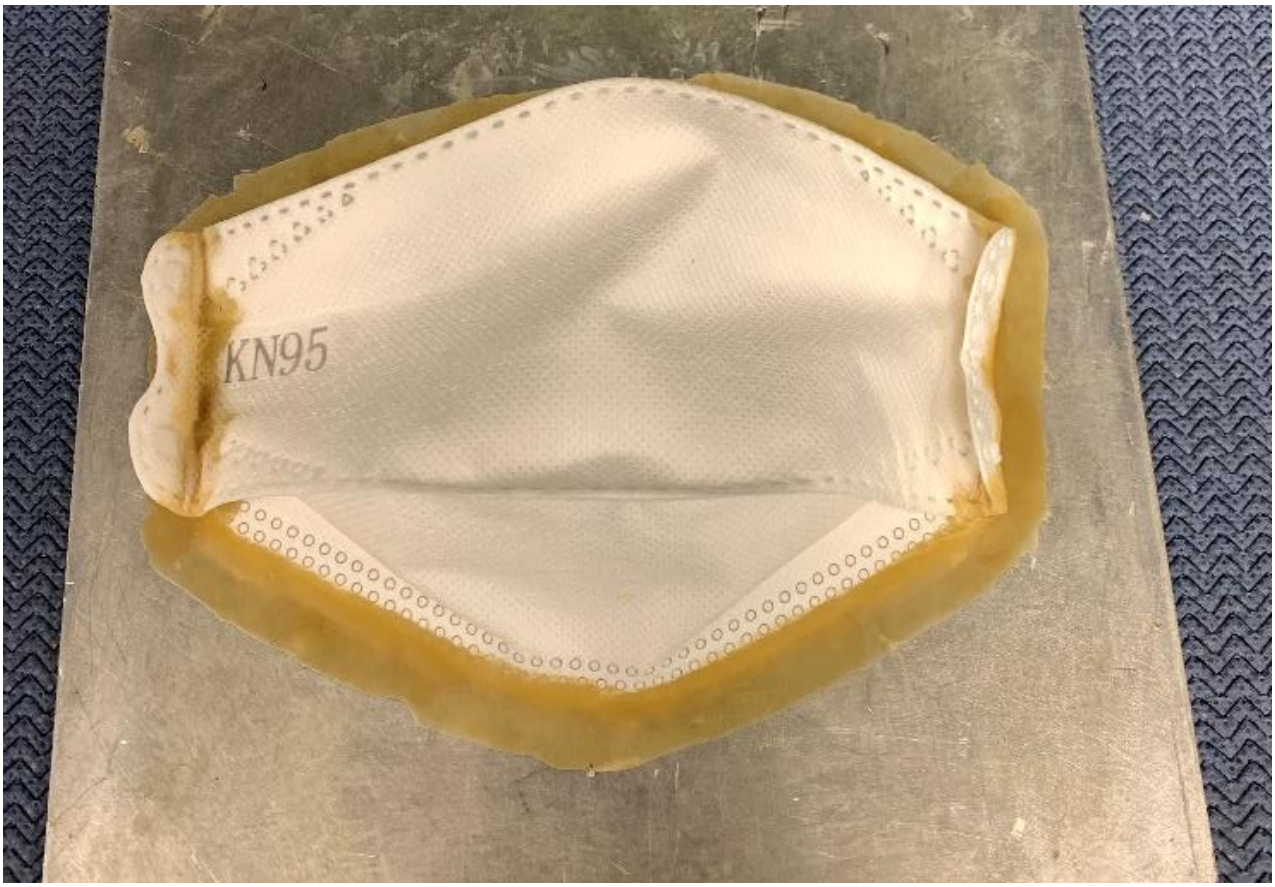


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MODEL

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