NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangzhou Tianyi Zhongliang Biotechnology Group Co., Ltd.

Model Tested: KN95 Disposable Protective Mask

Date Tested: April 27, 2020

These findings pertain to the Guangzhou Tianyi Zhongliang Biotechnology Group Co., Ltd., KN95 Disposable Protective Mask. The labeling for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

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.

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 observed was 97.29% and 87.20%, respectively. Nine respirators measured less than 95% efficiency. Only one respirator measured more than 95% 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 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 <u>Crisis Capacity Strategies</u> (during known <u>shortages</u>).

Evaluation of International Respirators



Pictures have been added to the

end of this report.

Test: Modified TEB-APR-STP-0059

Date Tested: April 27, 2020

Report Prepared: April 27, 2020

Manufacturer: Guangzhou Tianyi Zhongliang Biotechnology Group Co., Ltd.

Item Tested: KN95 Disposable Protective Mask **Country of Certification:** China (GB2626-2006)

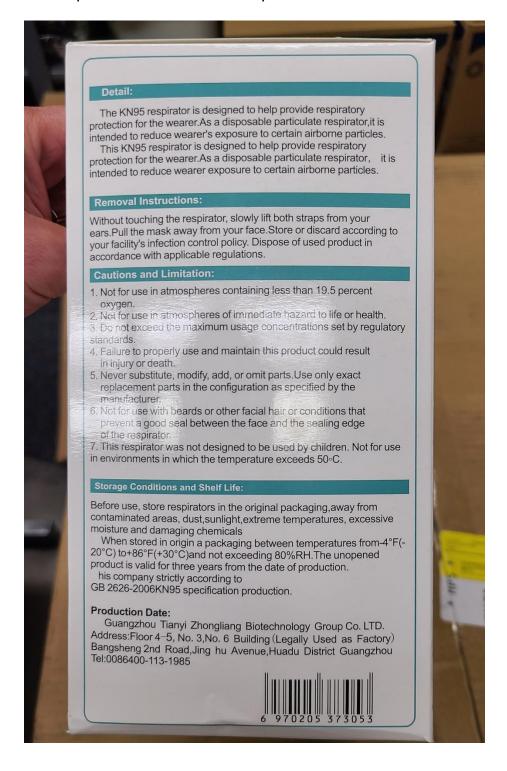
Initial Filter Initial Percent Maximum Flow Rate **Filter Efficiency Filter** Resistance Leakage Percent Leakage (LPM) (%) (mmH₂O) (%) (%) 85 8.37 8.61 91.39 1 6.1 2 85 6.2 9.10 9.10 90.90 3 85 5.5 8.86 9.33 90.67 4 85 6.1 8.06 8.06 91.94 5 85 5.9 9.19 9.27 90.73 6 85 6.0 7.75 7.57 92.43 7 85 2.30 2.71 97.29 4.2 85 5.9 8.76 8.76 91.24 8 9 85 5.5 11.3 11.9 88.10 10 85 5.5 12.8 87.20 11.9 Minimum Filter Efficiency: 87.20 Maximum Filter Efficiency: 97.29

- 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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