

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 [Crisis Capacity Strategies \(during known shortages\)](#).

Evaluation of International Respirators

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)

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	6.1	8.37	8.61	91.39
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	4.2	2.30	2.71	97.29
8	85	5.9	8.76	8.76	91.24
9	85	5.5	11.3	11.9	88.10
10	85	5.5	11.9	12.8	87.20
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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Detail:

The KN95 respirator is designed to help provide respiratory protection for the wearer. As a disposable particulate respirator, it is intended to reduce wearer's exposure to certain airborne particles.

This KN95 respirator is designed to help provide respiratory protection for the wearer. As a disposable particulate respirator, it is intended to reduce wearer exposure to certain airborne particles.

Removal Instructions:

Without touching the respirator, slowly lift both straps from your ears. Pull the mask away from your face. Store or discard according to your facility's infection control policy. Dispose of used product in accordance with applicable regulations.

Cautions and Limitation:

1. Not for use in atmospheres containing less than 19.5 percent oxygen.
2. Not for use in atmospheres of immediate hazard to life or health.
3. Do not exceed the maximum usage concentrations set by regulatory standards.
4. Failure to properly use and maintain this product could result in injury or death.
5. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
6. Not for use with beards or other facial hair or conditions that prevent a good seal between the face and the sealing edge of the respirator.
7. This respirator was not designed to be used by children. Not for use in environments in which the temperature exceeds 50°C.

Storage Conditions and Shelf Life:

Before use, store respirators in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals

When stored in original packaging between temperatures from -4°F (-20°C) to +86°F (+30°C) and not exceeding 80%RH. The unopened product is valid for three years from the date of production.

his company strictly according to GB 2626-2006KN95 specification production.

Production Date:

Guangzhou Tianyi Zhongliang Biotechnology Group Co. LTD.
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Bangsheng 2nd Road, Jing hu Avenue, Huadu District Guangzhou
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