NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Neolithic Tech Co., Ltd.
Model Tested: N95 Medical Protective Mask
Date Tested: May 13, 2020


Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-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 99.99% and 99.81%, respectively. All ten respirators measured more 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 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:** May 13, 2020

**Report Prepared:** May 14, 2020

**Manufacturer:** Neolithic Tech Co., Ltd.

**Item Tested:** N95 Medical Protective Mask

**Country of Certification:** China (EN149:2001+A1:2009)

<table>
<thead>
<tr>
<th>Filter</th>
<th>Flow Rate (LPM)</th>
<th>Initial Filter Resistance (mmH₂O)</th>
<th>Initial Percent Leakage (%)</th>
<th>Maximum Percent Leakage (%)</th>
<th>Filter Efficiency</th>
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<tbody>
<tr>
<td>1</td>
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<td>9.2</td>
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<td>85</td>
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<td>8.4</td>
<td>0.11</td>
<td>0.15</td>
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</tbody>
</table>

**Minimum Filter Efficiency:** 99.81  **Maximum Filter Efficiency:** 99.99

- 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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PRODUCT INFORMATIONS:

[Product Name] N95 Medical Protective Mask
[Brand Name] DOC
                  Aus: AS/NZS 1716:2012 P2
                  USA: ASTM F2100-2011 LOW(BFE)
[Mass Detection] Qualified
                  USA: ASTM F2100-2011
[Production Date] See the printed line of packing mark.
[Period of Validity] 2020.03-2022.02
[supplier] NEOLITHIC TECH CO., LTD
[Telephone] +86 20 84557556
[e-mail address] mask@form.net.cn
[Address] No.16, Haishun Road, Nancun Town, Panyu District, Guangzhou
INSTRUCTIONS:

1. Open the mask.
2. Hang the ear straps on both ears.
3. Adjust the nose clip.
4. Smooth the mask on both sides.

METTERS NEEDING ATTENTION:

- Do not use if package is damaged.
- Do not touch the contaminated surface when removing the mask.
- Please put it into the medical garbage can after use.

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>CERTIFICATE</th>
<th>Certificate No. held by Neolithic TECH Co., Ltd.</th>
<th>Official Website for Certificate Enquiry</th>
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<tr>
<td>EUR</td>
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<td>No. ICR Polska P6301883</td>
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[e-mail address] mask@form.net.cn
[Address] No.16, Haishun Road, Nancun Town, Panyu District, Guangzhou
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