NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shandong Haidike Medical Products Co., Ltd.
Model Tested: N95-V1 Medical Respirator
Date Tested: January 19, 2021

These findings pertain to the Shandong Haidike Medical Products Co., Ltd., N95-V1 Medical Respirator. The packaging for these respirators indicates they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

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 was 97.49% and 95.14%, 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.

This product has head bands/straps. 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).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: January 19, 2021
Report Prepared: January 19, 2021
Manufacturer: Shandong Haidike Medical Products Co., Ltd.
Item Tested: N95-V1 Medical Respirator
Country of Certification: China (GB19083-2010)

<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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>19.5</td>
<td>2.51</td>
<td>2.51</td>
<td>97.49</td>
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<tr>
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<td>85</td>
<td>22.9</td>
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<td>3</td>
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<td>4.86</td>
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<td>28.6</td>
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<td>27.0</td>
<td>3.91</td>
<td>3.92</td>
<td>96.08</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 95.14  Maximum Filter Efficiency: 97.49

- 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.

Pictures have been added to the end of this report.
NPPTL COVID-19 Response: International Respirator Assessment
N95-V1 MEDICAL RESPIRATOR
PROTECTIVE RESPIRATOR FOR MEDICAL USE

FOLDING TYPE
MEETS GB19083-2010 STANDARD
FILTRATION EFFICIENCY ≥ 95%

Performance:
1. The product should be clean, free of dirt, odor and discoloration. In addition, the product should not be damaged, cracked or show any deformations.
2. Filtration efficiency ≥ 95%

Contraindications:
This product should not be used by individuals who have allergic reactions to materials.

Warnings:
1. This product is intended for single-use only. Discard after use.
2. If the package is damaged, discard the product.

Storage and transportation conditions:
This product should be stored in environments that are cool, dry, clean, dark, free of corrosive gases, and well-ventilated. It should be transported in a clean and hygienic manner, and it should be isolated from fire sources.

Brand: wellbefore
Product Name: N95-V1 Medical Respirator
Layers: 1. Non-Woven Fabric
         2. Non-Woven Fabric
         3. Melt-Blown Fabric
         4. Melt-Blown Fabric
         5. Non-Woven Fabric
Implementation Standard: GB 19083-2010

Shandong Haidike Medical Products Co., Ltd.
Address: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China

www.wellbefore.com

MADE IN CHINA
DESIGNED IN TEXAS
NPPTL COVID-19 Response: International Respirator Assessment

USE INSTRUCTIONS:

1. Unfold the mask.

2. Put a mask on your face and wrap the head straps around your head.

3. Tighten the adjustable knobs on a head straps to ensure tight and comfortable fit.

4. Bend the nose pin to ensure good fit on the nose.

N95-V1
MEDICAL RESPIRATOR
PROTECTIVE RESPIRATOR FOR MEDICAL USE

FOLDING TYPE
MEETS GB19083-2010 STANDARD
FILTRATION EFFICIENCY ≥ 95%

STERILE EO STERILE

X No reuse
 Consult instructions for use
 Caution Keep dry
 Keep away from sunlight

WHITE 10 PCS INDIVIDUALLY WRAPPED

10 PCS INDIVIDUALLY WRAPPED
NPPTL COVID-19 Response: International Respirator Assessment

N95-V1 MEDICAL RESPIRATOR
PROTECTIVE RESPIRATOR FOR MEDICAL USE
FOLDING TYPE MEETS GB19083-2010 STANDARD FILTRATION EFFICIENCY ≥ 95%

CERTIFICATE OF CONFORMITY

Product Name: Medical Respirator
Type: N95-V1
Size: 11.5cm x 15cm
Materials: 60% Non-Woven fabric, 40% Melt-Blown fabric
Executive Standard: GB 19083-2010
Medical Device Registration No.: 20202140363
Medical Device Permit No.: 20200018
Storage and transportation conditions: This product should be stored in environments that are cool, dry, clean, dark, free of corrosive gases, and well-ventilated. It should be transported in a clean and hygienic manner, and it should be isolated from fire sources.
Quantity: 10 pcs/box

Manufacturer: Shandong Haidike Medical Products Co., Ltd.
Address: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China

MADE IN CHINA
N95-V1 MEDICAL RESPIRATOR
PROTECTIVE RESPIRATOR FOR MEDICAL USE

FOLDING TYPE

MEETS GB19083-2010 STANDARD
FILTRATION EFFICIENCY > 95%

Shandong Wellbefore Medical Products Co., Ltd.
Address: Tianfu Road, Danyang County, Huai'an City, Jiangsu Province, China

Brand: wellbefore
Product Name: N95-V1 Medical Respirator
Layers: 1. Non-Woven Fabric
2. Melt-Blown Fabric
3. Melt-Blown Fabric
4. Melt-Blown Fabric
5. Non-Woven Fabric

Implementation Standard: GB 19083-2010

www.wellbefore.com

5-LAYERS OF PROTECTION

Performance:
1. The product should be clean, free of dirt, odor, and discoloration. In addition, the product should not be damaged, cracked or show any deformations.
2. Filtration efficiency > 95%

Contraindications:
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