NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: AOK Tooling Limited (Shenzhenhai Medical Inc.)
Model Tested: 20180016
Date Tested: May 11, 2021

These findings pertain to the AOK Tooling Limited (Shenzhenhai Medical Inc.), model 20180016. The packaging and labeling indicate that it is a NIOSH-approved product, under approval number TC-84A-8131. The packaging for this product also indicates that it meets T/CTCA 7-2019 (the Chinese standard for Ordinary Protective Mask).

Ten respirators were submitted for evaluation. The samples were tested using the 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 was 99.58% and 92.16%, respectively. Eight respirators measured more than 95% filter efficiency. Two respirators measured less than 95% filter efficiency.

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-SP-0059

Date Tested: May 11, 2021

Report Prepared: May 14, 2021

Manufacturer: AOK Tooling Limited (Shenzhenhai Medical Inc.)

Item Tested: 20180016

Country of Certification: China (T/CTCA 7-2019); USA (42 CFR 84)

<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>15.4</td>
<td>6.13</td>
<td>6.13</td>
<td>93.87</td>
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<tr>
<td>2</td>
<td>85</td>
<td>18.4</td>
<td>7.84</td>
<td>7.84</td>
<td>92.16</td>
</tr>
<tr>
<td>3</td>
<td>85</td>
<td>17.2</td>
<td>2.32</td>
<td>2.32</td>
<td>97.68</td>
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<td>4</td>
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<td>5</td>
<td>85</td>
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<td>97.05</td>
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<tr>
<td>6</td>
<td>85</td>
<td>16.1</td>
<td>1.07</td>
<td>1.07</td>
<td>98.93</td>
</tr>
<tr>
<td>7</td>
<td>85</td>
<td>18.8</td>
<td>2.33</td>
<td>2.33</td>
<td>97.67</td>
</tr>
<tr>
<td>8</td>
<td>85</td>
<td>18.0</td>
<td>0.46</td>
<td>0.46</td>
<td>99.54</td>
</tr>
<tr>
<td>9</td>
<td>85</td>
<td>17.8</td>
<td>0.38</td>
<td>0.42</td>
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<td>10</td>
<td>85</td>
<td>17.7</td>
<td>3.71</td>
<td>3.71</td>
<td>96.29</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 92.16%  Maximum Filter Efficiency: 99.58%

• 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.
V Fold N95 B Mask

**Name:** V Fold N95 B Mask (非医用)  
**Model:** 20180016  
**Spec.:** ☑ L ☐ M ☐ S  
**Quantity:** 10PCS  
**执行标准:** 团标 T/CTCA 7-2019  
**NIOSH number:** TC-84A-8131  
**Main components:** Silicone 56%, Non-woven 28%, Melt-blown non woven 6%, Elastic 5%, Nose Piece 2%, Adjustment clip 3%.  
**Distributor:** AOK Tooling Ltd.  
**Manufacturer:** Shenzhonghai Medical Inc.  
**Add.:** #8, Longtian 3Rd, Longtian Street, Pingshan Dist., Shenzhen, China  
**Tel:** 86-0755-84112290

**Expiration date:** 3 years  
**Production date:** 2020-04-11  
**Lot No.:** 202004110100  

Made in China
**NPPTL COVID-19 Response: International Respirator Assessment**

<table>
<thead>
<tr>
<th><strong>Name/Model/Spec./Standard</strong></th>
<th><strong>Value</strong></th>
</tr>
</thead>
</table>
| Name                          | 折叠式N95口罩 (非医用)  
V Fold N95 B Mask (Non-Medical) |
| Model                         | 20180016  |
| Spec.                         | L         |
| Standard                      | 团标 T/CTCA 7-2019 |

<table>
<thead>
<tr>
<th><strong>NIOSH number</strong></th>
<th><strong>Value</strong></th>
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<tr>
<td>TC-84A-8131</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Main components</strong></th>
<th><strong>Value</strong></th>
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</thead>
<tbody>
<tr>
<td>硅胶56%，无纺布28%，熔喷布6%，松紧带5%，鼻梁条2%，调节扣3%</td>
<td>Silicone 56%, Non-woven 28%, Melt-blown non woven 6%, Elastic 5%, Nose Piece 2%, Adjustment Clip 3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Production date/Lot No./Expiration date</strong></th>
<th><strong>Value</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Production date</td>
<td>2020-04-11</td>
</tr>
<tr>
<td>Lot No.</td>
<td>202004110100</td>
</tr>
<tr>
<td>Expiration date</td>
<td>3 years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Distributor/Manufacturer/Address/Tel</strong></th>
<th><strong>Value</strong></th>
</tr>
</thead>
</table>
| Distributor                            | 深圳市飞速精密模具有限公司  
AOK Tooling Ltd. |
| Manufacturer                           | 深中海医疗用品（深圳）有限公司  
Shenzhenhai Medical Inc. |
| Address                                | 深圳市坪山区龙田街道龙田三路8号  
#8, Longtian 3Rd, Longtian Street,  
Pingshan Dist, Shenzhen, China |
| Tel                                     | 86-0755-84112290 |
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WORKPLACE/OCCUPATIONAL USER INSTRUCTIONS

V Post H55 B Mask | Large Size
When it is being worn, be aware that this is a large size mask and that other sized masks may fit better.

User Instructions

IMPORTANT: Keep these instructions for reference
This respirator contains components made from natural rubber latex.

WARNING
This respirator helps prevent against certain particles. Mismatches may result in sickness or death. For proper use, see user instructions.

Respirator Use:
For protection against particles such as those from metal, wood, minerals, coal, and raw, vegetable, animal, and certain other substances as well as liquid or non-aerosolized particles from sprays that do not use air or vapor.

Do Not Use For:
Chemical vapor, including those present in paint stripping operations, or any toxic substance such as ammonia or sandblasting for all aerosols. This respirator does not filter out chemicals.

Biological Particles
This respirator can help reduce inhalation exposures to certain airborne biological particles but cannot eliminate the risks of contracting infection, illness, or disease.OSHA and other government agencies have not established safe exposure limits for these contaminants.

Additional Use Limitations
1. Inspect the respirator for damage. If your respirator appears damaged, DO NOT USE IT. Replace it with a new one.
2. Failure to follow all instructions and use limitations for this respirator may result in severe or life-threatening injury.
3. Do not share facial hair, including jewelry, glasses, clothing, or anything else that will prevent proper placement or cause between your face and the respirator.
4. Do not alter, abuse, or misuse the respirator.
5. Leave the respirator area immediately and contact appropriate medical assistance if you are feeling ill due to irritation of other discomfort.
6. This respirator is designed for use by adults who are properly trained in the use and limitations. This respirator is not designed to be used by children.
7. Before occupationally using this respirator, it is required to implement a respiratory protection program as required by federal and state/local government regulations.

Manufactured by:
AOK Tooling Limited
Shen Zhen, China

N95 Particulate Filter (95% Filtration Efficiency) Effective Against Particulate Aerosols that May Contain Blood and Vomitus. N95 masks provide a good seal around the face. They are not effective against gases, vapors, or odors. N95 masks do not protect against chemical vapors or liquids. This respirator is not suitable for use by children.

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION

TC | Protection | Respirator | Caution and Limitations
---|---|---|---
MA-131 | N95 | 20190104 | X

1. PROTECTION
N95 Particulate Filter (95% Filtration Efficiency) Effective Against Particulate Aerosols that May Contain Blood and Vomitus. N95 masks provide a good seal around the face. They are not effective against gases, vapors, or odors. N95 masks do not protect against chemical vapors or liquids. This respirator is not suitable for use by children.

2. CAUTIONS AND LIMITATIONS
A. Not for use in atmospheres containing less than 19.5% oxygen.
B. Not for use in atmospheres immediately poisonous to life or health.
C. Do not exceed maximum use concentration established by regulatory standards.
D. Failure to properly wear and maintain this product could result in injury or death.
E. All approved respirators shall be selected, fitted, used, and maintained in accordance with OSHA and other applicable regulations.
F. This respirator is not suitable for use by children.
G. This respirator is not suitable for use by children.
H. This respirator is not suitable for use by children.
I. This respirator is not suitable for use by children.
J. This respirator is not suitable for use by children.
K. This respirator is not suitable for use by children.
L. This respirator is not suitable for use by children.
M. This respirator is not suitable for use by children.
N. This respirator is not suitable for use by children.
O. This respirator is not suitable for use by children.
P. This respirator is not suitable for use by children.

PIN 5-16-0015 Rev A1
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