NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: AOK Tooling Limited (Shenzhonghai Medical Inc.)
Model Tested: 20180016
Date Tested: May 13, 2021

These findings pertain to the AOK Tooling Limited (Shenzhonghai 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 99.59% and 96.98%, respectively. All ten respirators measured more 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).
Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: May 13, 2021

Report Prepared: May 14, 2021

Manufacturer: AOK Tooling Limited (Shenzhonghai 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>19.1</td>
<td>0.46</td>
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<td>2</td>
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<tr>
<td>3</td>
<td>85</td>
<td>15.0</td>
<td>0.93</td>
<td>1.02</td>
<td>98.98</td>
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<td>7</td>
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<td>0.60</td>
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<tr>
<td>8</td>
<td>85</td>
<td>15.7</td>
<td>2.77</td>
<td>3.02</td>
<td>96.98</td>
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<tr>
<td>9</td>
<td>85</td>
<td>15.9</td>
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<td>10</td>
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<td>11.8</td>
<td>0.65</td>
<td>0.89</td>
<td>99.11</td>
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</table>

Minimum Filter Efficiency: 96.98%
Maximum Filter Efficiency: 99.59%

- 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.
V Fold N95 B Mask

Name: V Fold N95 B Mask (非医用)
Model: 20180016
Spec.: ☑️ XL ☐ 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: Shenzhenhui 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
### 合格证 Certification

| Name | 折叠式N95口罩 (非医用)  

V Fold N95 B Mask (Non-Medical) |
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td>Model</td>
<td>20180016</td>
</tr>
<tr>
<td>Spec.</td>
<td>L</td>
</tr>
<tr>
<td>Standard</td>
<td>团标 T/CTCA 7-2019</td>
</tr>
<tr>
<td>NIOSH number</td>
<td>TC-84A-8131</td>
</tr>
</tbody>
</table>
| Main components | 硅胶56％，无纺布28％，熔喷布6％，松紧带5％，鼻梁条2％，调节扣3％  

Silicone 56%, Non-woven 28%, Melt-blown non woven 6%, Elastic 5%, Nose Piece 2%, Adjustment Clip 3% |
| Production date | 2020-04-11 |
| Lot No. | 202004110100 |
| Expiration date | 3 years |
| 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. |
| Add. | 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 |
WORKPLACE/OCCUPATIONAL USER INSTRUCTIONS
2018016-L V Fold N95 B Mask - Large Size
When folding or removing, be aware that this is a large size mask and that other sizes may not fit.

User Instructions
(IMPORTANT) Keep these instructions for reference. The respirator contains components from natural rubber latex.

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

Respirator Use:
For protection against particles such as those from metal, wood, minerals, coal, lead, cements, polystyrene, and certain other insoluble dusts as well as gases or vapors or other substances such as liquids, or fumes. The respirator does not supply oxygen.

Do Not Use For:
Gases and vapors, including those present in paints, spray cleaning, or any toxic substances such as cigarette smoke, or gas-stovetop or oil stovetop. This respirator does not supply oxygen.

Biological Particles
This respirator can trap particles in the air. But it cannot protect against all conditions.

Additional Use Limitations
1. Impact to the respirator for damage. Do not use a damaged respirator.
2. Failure to follow all instructions and use instructions for the respirator as intended to wear the respirator during all times of exposure may result in sickness or death.
3. Do not allow for use by, or by anyone other than the user.
4. Do not store, abuse, or misuse the respirator.
5. Never fit the respirator in an area immediately and constantly under conditions that will cause discomfort, irritation, or other distressing effects.
6. This respirator is designed for use by adults and is not intended for use by children or any other person.
7. Before occupational use of this respirator, a written respirator protection program must be implemented.

Time Use Limitations:
The respirator has been designed for use in the workplace for a maximum of 8 hours. The face mask shall be replaced immediately if the respirator is damaged.

WASH YOUR HANDS BEFORE PUTTING ON AND AFTER TAKING OFF THE MASK.

Instructions for Use:
1. Place the breathing tube on the side of the schedule as shown in the figure below. Insert the mask into the nose on the side of the respirator and fit it against the entire surface of your face.
2. The respirator should be worn on the nose and around the respirator to conform to your face and the respirator shall be placed over the nose.
3. Adjust the nose bridge and adjust the respirator to conform with your face.
4. Make sure that the respirator is not blocking the proper wearing of the respirator.
5. Clean the mouth and nose area with the respirator.
6. Remove the respirator from your mouth and nose area.
7. To remove the respirator, remove the head and mask area while maintaining the proper wearing of the respirator on the face.

Personal Instructions:
1. Do not use the respirator if the respirator is damaged or if the respirator is not properly worn.
2. If the respirator is damaged or if the respirator is not properly worn, remove the respirator immediately.

Manufactured by:
AOK Tooling Limited
Shen Zhen, China

AOK Tooling Limited
Long Tian Village, Kang Tali Town
Pinghu County, Shen Zhen
China
TEL: 86 755 84119972

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

<table>
<thead>
<tr>
<th>TC</th>
<th>Protection</th>
<th>Cautions and Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>04A-8131</td>
<td>K95</td>
<td>X</td>
</tr>
</tbody>
</table>

1. Protection:
N95 Particulate Filter (95% filter efficiency) (FFP1/FFP2) against particulate matter with a face of 0.3 microns or less, as applicable.

2. Cautions and Limitations:
A. Do not use in atmospheres containing less than 195% oxygen.
B. Do not use in atmospheres that are immediately dangerous to life or health.
C. Do not exceed maximum usage concentrations established in respiratory standards.
D. Failure to properly care for this product could result in injury or death.
E. As directed, respiratory protection shall be selected, fitted, used, and maintained in accordance with OSHA, a: a: and other applicable regulations.
F. Newer dusts, chemicals, acids, or dusts. Use only mask replacement parts or the respirator as indicated by the manufacturer.
G. Follow the instructions, and the manufacturer's instructions for information on use and maintenance of these respirators.
H. Mow does not evaluate respirators for use as surgical mask.
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