

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: AOK Tooling Limited (Shenzhonghai Medical Inc.)

Model Tested: 20180016

Date Tested: May 11, 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 99.58% 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 \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: May 11, 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)

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	15.4	6.13	6.13	93.87
2	85	18.4	7.84	7.84	92.16
3	85	17.2	2.32	2.32	97.68
4	85	14.4	0.79	1.02	98.98
5	85	15.3	2.95	2.95	97.05
6	85	16.1	1.07	1.07	98.93
7	85	18.8	2.33	2.33	97.67
8	85	18.0	0.46	0.46	99.54
9	85	17.8	0.38	0.42	99.58
10	85	17.7	3.71	3.71	96.29
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.

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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: 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

合格证 Certification	
产品名称 Name	折叠式N95口罩 (非医用) V Fold N95 B Mask (Non-Medical)
产品型号 Model	20180016
产品规格 Spec.	L
执行标准 Standard	团标 T/CTCA 7-2019
NIOSH number	TC-84A-8131
主要成分 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%
生产日期 Production date	2020-04-11
生产批号 Lot No.	202004110100
有效期 Expiration date	3 years
经销商 Distributor	深圳市飞速精密模具有限公司 AOK Tooling Ltd.
生产企业 Manufacturer	深中海医疗用品 (深圳) 有限公司 Shenzhonghai Medical Inc.
生产地址 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
联系电话 Tel	86-0755-84112290



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WORKPLACE/OCCUPATIONAL USER INSTRUCTIONS

20180016-L V Fold N95 B Mask : Large Size

When fit testing or reordering, 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 no compounds from natural rubber latex.

WARNING

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

Respirator Use:

For protection against particles such as those from metal, wood, minerals, coal, iron ore, cotton, pollen, flour, and certain other substances as well as liquid or non-oil based particles from sprays that do not also emit oil aerosols or vapors.

Do Not Use For:

Gases and vapors, including those present in paint spraying operations, or any toxic substance such as asbestos or sandblasting or for oil aerosols. This respirator does not supply oxygen.

Biological Particles

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

Additional Use Limitations

- Inspect the respirator for damage. If your respirator appears damaged, DO NOT USE IT. Replace it with a new one.
- Failure to follow all instructions and use limitations for this respirator and/or failure to wear this respirator during all times of exposure may result in sickness or death.
- Do not allow facial hair, hair, jewelry, glasses, clothing, or anything else to prevent proper placement or come between your face and the respirator.
- Do not alter, abuse or misuse the respirator.
- Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
- This respirator is designed for use by adults who are properly trained in their use and limitations. This respirator is not designed to be used by children.
- Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the local government requirements. In the United States, employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training, and fit testing.

Available Sizes:	Part Number
Extra Large	20180016-XL
Large	20180016-L
Medium	20180016-M
Small	20180016-S

Time Use Limitations

If the respirator becomes damaged, soiled, or breathing becomes difficult, leave the contaminated area immediately and replace the respirator.

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

Instructions for Use:

- Facing the respirator on the side of a silicone seal, and make the nose clip in the top of the respirator, then hold the respirator with hands to make it fixed with the face and against the chin.
- Pull the lower elastic band over the head and place it under the neck and under the ear.
- Pull the upper elastic band over the head and place it above the ear.
- Adjust the respirator position, slightly press the nose piece use your hand until the silicone seal around the respirator is comfortable with your face.
- Adjust the elastic band and the buckle to the appropriate felt strength of elastic band.
- Check the fit of the respirator to the face:
 - Cover the respirator with both hands to avoid affecting the position of the respirator on the face.
 - Make a quick inspiration. If air leaks from the edge of the respirator, please re-adjust the elastic band; if you can not get a good fit, repeat steps 1-5.

Removal Instructions:

- Cup respirator in hand to maintain position on face and pull bottom strap over your head.
- Hold respirator in position and pull top strap over your head and remove respirator.



Manufactured by:
AOK Tooling Limited
Shen Zhen, China



AOK Tooling Limited
Long Tian Village, Keng Zi Town
Pingshan District, Shen Zhen
China
TEL 86 0755 84111912



THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		20180016-L	
84A-8131	N95	X	ABCJMNP

1. PROTECTION

N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5% oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- J - Failure to properly use and maintain this product could result injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.

PN B-18-S028 Rev A/1

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