

NIOSH Reference: TN-18877 Mfr. Reference: AOK07 Centers for Disease Control OPY and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL)

P.O. Box 18070

Pittsburgh, PA 15236-0070 Phone: 412-386-4000 Fax: 412-386-4051 March 21, 2013

Mr. Jerry Teng, President AOK Tooling Limited No.3 of Longtian 3 Road, Longtian Village Kengzi Town, Longgang District Shenzhen China

Dear Mr. Teng:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted January 3, 2013. This request was for an approval of the part number 20100032-002 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix 20100032-002Assembly\_Matrix\_AMf.xlsx. In addition, the AOK Tooling Limited Quality Manual, (Reference Number FS-QM-2009, revision number D/7, with a validation date of Nov 30<sup>th</sup> 2011), was submitted for review.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. The approval number TC-84A-6269 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level.

NIOSH has also reviewed the quality manual presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The CD enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

A copy of the quality manual will be retained by NIOSH and incorporated into our files. Any future changes to this accepted quality document must be submitted to NIOSH for a modification of this accepted quality system.

Sincerely yours,

Jeffrey Peterson

Acting Chief, Technology Evaluation Branch National Personal Protective Technology Laboratory

Enclosures



National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory Technology Evaluation Branch Certification, Evaluation and Testing Section P.O. Box 18070 Pittsburgh, PA 15236

## TEST REPORT

Task Number: TN-18877

Manufacturer: AOK Tooling Limited

Prepared by: Jeremy Brannen

Tests Conducted by: Jeremy Brannen

Date: February 13, 2013

Respirator Tested: 20100032-002

### **Background Information**

In an application accepted January 3, 2013 AOK Tooling requested an approval of the part number 20100032-002 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix 20100032-002Assembly Matrix AMf.xlsx. In addition, the AOK Tooling Limited Quality Manual, (Reference Number FS-QM-2009, revision number D/7, with a validation date of Nov 30<sup>th</sup> 2011), was submitted for review.

#### Tests Assigned

Test Description	STP Number	Reference	
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180	
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180	
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059	84.181	

### **Overall Results**

The items tested passed laboratory testing.

### **Individual Test Results**

See the attached test data sheets.

# National Institute for Occupational Safety and Health Respirator Branch Test Data Sheet



Task Number: TN-18877 Reference No.: CFR 84.180

Test: Exhalation Resistance Test STP No.: 3

Manufacturer: AOK Tooling Limited

Filter Type: Filter Only

Item Tested: 20100032-002

ample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	14.7	PASS
2	25	14.7	PASS
3	25	14.7	PASS

Overall Result: PASS

#### Comments:

Was all equipment verified to be in calibration throughout all testing? (e) Yes () No

Signature: Date: 2/13/2013

**Engineering Technician** 

# National Institute for Occupational Safety and Health Respirator Branch Test Data Sheet



Task Number: TN-18877

Reference No.: CFR 84.180 STP No.: 7

Test:

Inhalation Resistance Test

Manufacturer: AOK Tooling Limited

Item Tested: 20100032-002

Filter Type: Filter Only

Maximum Allowable Resistance Actual Resistance (MM of H2O) (MM of H2O)				
Sample		Inhalation	Inhalation	Result
1		35	15.5	PASS
2	18:	35	15.2	PASS
3		35	16.0	PASS

Overall Result: PASS

Date: 2/13/2013

Signature:

**Engineering Technician** 

Task Number: TN-18877

Reference No.: CFR 84.180

STP No.: 7

Inhalation Resistance Test

Manufacturer: AOK Tooling Limited

Item Tested: 20100032-002

Comments:

Was all equipment verified to be in calibration throughout all testing?

(e) Yes ( ) No

**Engineering Technician** 

Date: 2/13/2013

# National Institute for Occupational Safety and Health

Respirator Branch

**Test Data Sheet** 

Task Number: TN-18877

Reference No.: CFR 84.181

Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: AOK Tooling Limited

Item Tested: 20100032-002

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	18.6	5.00	1.120	1.120	PASS
2	85	19.3	5.00	1.750	1.750	PASS
3	85	18.5	5.00	1.170	1.170	PASS
4	85	18.6	5.00	1.810	1.810	PASS
5	85	18.2	5.00	1.470	1.470	PASS
6	85	17.6	5.00	1.650	1.650	PASS
7	85	17.6	5.00	1.230	1.230	PASS
8	85	20.0	5.00	1.280	1.280	PASS
9	85	17.8	5.00	2.090	2.090	PASS
10	85	18.5	5.00	0.988	0.988	PASS
11	85	17.6	5.00	1.890	1.890	PASS
12	85	18.6	5.00	0.740	0.774	PASS
13	85	17.5	5.00	1.500	1.500	PASS
14	85	17.0	5.00	1.220	1.220	PASS
15	85	19.9	5.00	1.370	1.370	PASS
16	85	19.6	5.00	2.210	2.210	PASS
17	85	18.4	5.00	2.220	2.220	PASS
18	85	18.7	5.00	1.750	1.750	PASS
19	85	18.7	5.00	1.630	1.630	PASS
20	85	19.0	5.00	1.420	1.660	PASS

Overall Result: PASS

Signature:

Date: 2/13/2013

**Engineering Technician** 

Task Number: TN-18877 Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95 STP No.: 59

Manufacturer: AOK Tooling Limited

Item Tested: 20100032-002

Comments:

Was all equipment verified to be in calibration throughout all testing?

Date: 2/13/2013

**Engineering Technician** 

Signature:

# Harvey, Karen (CDC/NIOSH/NPPTL)

From: Peterson, Jeff (CDC/NIOSH/NPPTL)
Sent: Friday, March 22, 2013 3:26 PM

To: Harvey, Karen (CDC/NIOSH/NPPTL); Zubasic, Dawn (CDC/NIOSH/NPPTL)

Cc: Pouchot, Thomas D. (CDC/NIOSH/NPPTL); Stein, Robert (CDC/NIOSH/NPPTL)

Subject: FW: TN18877AOKnew.doc, TN18877 Approval Letter

Attachments: TN18877AOKnew.doc; 18877ApprovalConcurrence.xls; 18877rep.doc

#### Please finalize for signature

----Original Message----

From: Stein, Robert (CDC/NIOSH/NPPTL) Sent: Friday, March 22, 2013 10:57 AM To: Peterson, Jeff (CDC/NIOSH/NPPTL)

Cc: Harvey, Karen (CDC/NIOSH/NPPTL); Zubasic, Dawn (CDC/NIOSH/NPPTL); Pouchot, Thomas D. (CDC/NIOSH/NPPTL)

Subject: FW: TN18877AOKnew.doc, TN18877 Approval Letter

#### Jeff:

I concur with the draft letter as prepared by Tom.

Bob

----Original Message----

From: Pouchot, Thomas D. (CDC/NIOSH/NPPTL)

Sent: Tuesday, March 19, 2013 8:13 AM To: Stein, Robert (CDC/NIOSH/NPPTL)

Subject: TN18877AOKnew.doc, TN18877 Approval Letter

Bob,

Attached are the approval letter, test report and concurrence sheet for TN18877 (AOK). The file will be in your office shortly.

Please review and concur as appropriate.

Any issues, please contact me.

Tom Pouchot Ext 4036

The message is ready to be sent with the following file or link attachments:

TN18877AOKnew.doc 18877ApprovalConcurrence.xls 18877rep.doc

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

### Concurrence - Process in order shown, sending the project to the next person on the list. TN18877(AOK)

Author - be sure to complete the checklist to include all relevant information for the Program Assistant.

Author T Pouchot	Date sent to peer review and MSHA (if applicable) 3/19/2013
Pouchot	3/19/2013
MSHA representative	Date sent to Secretary N/A
Certification Team Leader	Date sent to Branch Chief (cc: Secretary)
RRS for J. Peterson	3/22/2013
Branch Chief	Date sent to Secretary
JAP	3/22/2013
Secretary	Date Ready for Signature
KH	3/25/2013
Secretary	Date Mailed CD? Y/N PDF? Y/N
KH	3/25/2013 Y N