



NIOSH Reference: TN-18228  
Mfr. Reference: SSPMS6115a

Centers for Disease Control  
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  
January 31, 2012

Guoping Jiang, Technical Director  
Suzhou Sanical Protective Product Manufacturing Co., Ltd.  
No. 6, Xihenggang Street, Yangchenghu Town  
Xiangcheng District  
Suzhou City, 215002  
China

Dear Guoping Jiang:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted December 16, 2011. This request was for approval of the models MS6115 filtering facepiece air purifying respirators (APR), part numbers SC-MS6115 and SC-MS6115L, for protections against particulates at a N95 filter efficiency level, reference assembly matrix MS6115Amb.xls. In addition, the Suzhou Sanical Protective Product Manufacturing Company Quality Manual, document number SC-QM-2011, revision A/0 and effective date 2011-03-11 was presented for review.

This request is granted. Approval is 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. Approval number TC-84A-5530 has been assigned. These respirators are approved for protection 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 respirators approval label. The abbreviated labels have 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 assemblies consist 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 labels 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 respirators by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that these respirators have met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirator 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.

Sincerely yours,



Heinz W. Ahlers  
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-18228

**Manufacturer:** Suzhou Sanical Protective Product Manufacturing Co., LTD

**Prepared by:** Jeremy Brannen

**Tests Conducted by:** Jeremy Brannen / Keith Foltz

**Date:** January 11, 2012

**Respirator Tested:** SC-MS6115/SC-MS6115L

#### Background Information

In an application accepted December 16, 2011 Suzhou Sanical Protective Product Manufacturing requested approvals of the models MS6115 filtering facepiece air purifying respirators (APR), part numbers SC-MS6115 and SC-MS6115L, for protections against particulates at a N95 filter efficiency level, reference assembly matrix MS6115AMB.xls. In addition, the Suzhou Sanical Protective Product Manufacturing Company Quality Manual, document number SC-QM-2011, revision A/0 and effective date 2011-03-11 was presented for review.

#### Tests Assigned

<u>Test Description</u>	<u>STP Number</u>	<u>Reference</u>
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-18228

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Filter Type: Filter Only

Item Tested: SC-MS6115 / SC-MS6115L

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	12.4	PASS
2	25	12.7	PASS
3	25	12.4	PASS
4	25	11.9	PASS
5	25	12.2	PASS
6	25	11.9	PASS

Overall Result: PASS


Comments:

Samples 1-3 were tested using the SC-MS6115, and samples 4-6 were tested using the SC-MS6115L.

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

Yes  No

Signature:

  
Engineering Technician

Date: 1/11/2012

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



Task Number: TN-18228

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested: SC-6115 / SC-MS6115L

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H <sub>2</sub> O)	Actual Resistance (MM of H <sub>2</sub> O)	Result
	Inhalation	Inhalation	
1	35	12.7	PASS
2	35	12.7	PASS
3	35	13.0	PASS
4	35	11.9	PASS
5	35	11.9	PASS
6	35	11.9	PASS

**Overall Result:** PASS

Signature:



Engineering Technician

Date: 1/11/2012

Task Number: TN-18228

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Suzhou Sanical Protective Product Manufacturing


Item Tested: SC-6115 / SC-MS6115L

**Comments:**

Samples 1-3 were tested using the SC-MS6115, and samples 4-6 were tested using the SC-MS6115L.

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

Yes  No

Signature: 

Date: 1/11/2012

Engineering Technician

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



Task Number: TN-18228

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested: SC-MS6115

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	14.2	5.00	0.913	0.913	PASS
2	85	14.4	5.00	0.509	0.509	PASS
3	85	15.0	5.00	0.982	0.982	PASS
4	85	14.2	5.00	0.621	0.621	PASS
5	85	14.6	5.00	0.817	0.817	PASS
6	85	14.3	5.00	1.150	1.150	PASS
7	85	14.5	5.00	0.961	0.961	PASS
8	85	14.1	5.00	0.474	0.474	PASS
9	85	14.5	5.00	0.361	0.361	PASS
10	85	14.6	5.00	0.616	0.616	PASS
11	85	14.1	5.00	0.652	0.652	PASS
12	85	14.8	5.00	1.220	1.220	PASS
13	85	14.8	5.00	0.787	0.787	PASS
14	85	14.7	5.00	1.630	1.630	PASS
15	85	15.3	5.00	1.080	1.080	PASS
16	85	15.7	5.00	0.675	0.675	PASS
17	85	15.4	5.00	0.792	0.792	PASS
18	85	15.6	5.00	0.539	0.539	PASS
19	85	14.9	5.00	0.695	0.695	PASS
20	85	14.2	5.00	0.589	0.589	PASS

Overall Result: PASS

Signature:

Engineering Technician

Date: 1/11/2012

Task Number: TN-18228

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested: SC-MS6115

**Comments:**

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

Yes  No

Signature:



Engineering Technician

Date: 1/11/2012



Approval - Concurrence

**Concurrence - Process in order shown, sending the project to the next person on the list.**

TN18228 (SSP)

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

Author	Date sent to peer review and MSHA (if applicable)
TDP 01/26/2012	1/26/2012

MSHA representative	Date sent to Secretary	N/A

Certification Analyst	Date sent to Branch Chief (cc: Secretary)
T. Thornton	1/27/2012

Branch Chief	Date sent to Secretary
hwa	1/30/2012

Secretary	Date ready for signature
LL	1/31/2012

Secretary	Date mailed
LL	2/1/2012

**Luncinski, Lillian (CDC/NIOSH/NPPTL)**

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**From:** Ahlers, Heinz W. (CDC/NIOSH/NPPTL)  
**Sent:** Monday, January 30, 2012 3:48 PM  
**To:** Luncinski, Lillian (CDC/NIOSH/NPPTL); Peterson, Jeff (CDC/NIOSH/NPPTL); Pouchot, Thomas D. (CDC/NIOSH/NPPTL); Thornton, Terry L. (CDC/NIOSH/NPPTL)  
**Subject:** FW: TN18228SSPnew.doc, TN18228 Approval Letter  
**Attachments:** 18228 Concurrence and checklist.xls; TN18228SSPnew.doc; 18228rep.doc

I concur

-----Original Message-----

**From:** Thornton, Terry L. (CDC/NIOSH/NPPTL)  
**Sent:** Friday, January 27, 2012 8:00 AM  
**To:** Ahlers, Heinz W. (CDC/NIOSH/NPPTL)  
**Cc:** Luncinski, Lillian (CDC/NIOSH/NPPTL); Harvey, Karen (CDC/NIOSH/NPPTL)  
**Subject:** FW: TN18228SSPnew.doc, TN18228 Approval Letter

Approved and forwarded for your signature. tlt

-----Original Message-----

**From:** Pouchot, Thomas D. (CDC/NIOSH/NPPTL)  
**Sent:** Thursday, January 26, 2012 2:37 PM  
**To:** Thornton, Terry L. (CDC/NIOSH/NPPTL)  
**Subject:** TN18228SSPnew.doc, TN18228 Approval Letter

Terry,

Attached are the approval letter, test report and concurrence checklist for TN18228 (SSP). The file will be in your office shortly.

Any issues please contact me.

Tom Pouchot  
Ext 4036

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

TN18228SSPnew.doc  
18228Concurrence and checklist.xls  
18228rep.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.