

and Prevention (CDC)

NIOSH Reference: TN-20185 SSPMS8225a National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPT) 626 Cochrans Mill Road

Pillsburgh, PA 15236-0070 Phone: 412-386-4000 412-386-4051 June 26, 2015

Mr. Guoping Jiang Technical Director Suzhou Sanical Protective Product Manufacturing Company, Ltd. No. 21, Xihenggang Street, Yangchenghu Town Xiangcheng District Suzhou City 215002 China

Dear Mr. Jiang:

Mfr. Reference:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted April 27, 2015. This request was for approval of the MS8225 air purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix MS8225AMa.xls revision A/1, dated June 18, 2015.

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. Approval number TC-84A-7447 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

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 this respirator has met the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).

Page 2 - Mr. Guoping Jiang - TN-20185

Suzhou Sanical

Suzhou Sanical

Suzhou Sanical

Suzhous 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 Suzhou Sanical modification of this approval must be granted before changes are made.

Sincerely yours,

David Chirdon

Chief, Conformity Verification and Standards Development Branch

Suzhou Sanical

Thou Sanic

Suzho

Enclosures Suzhou Sanical



National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory Technology Evaluation Branch Certification, Evaluation and Testing Section 626 Cochrans Mill Road Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-20185

Manufacturer: Suzhou Sanical Protective Product Manufacturing Co., Ltd.

Prepared by: Nichole Petitta

Tests Conducted by: Nichole Petitta

Date: June 3, 2015

Respirator Tested: MS8225 N95

Background Information

Respirator tested as per test request.

Tests Assigned

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

Overall Results

The respirator system tested met the requirements of all the procedures listed above

National Institute for Occupational Safety and Health Respirator Branch

Test Data Sheet



Task Number: TN-20185

Reference No.: CFR 84.180

Test:

Exhalation Resistance Test

STP No.: 3

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Filter Type:

Filter Only

Item Tested:

MS8225 N95

ampłe	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
	25	9.8	PASS
2	25	9.8	PASS
3	25	9.8	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000034.

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

Signature:

Date:

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



Task Number: TN-20185

Reference No.: CFR 84,180

Test:

Inhalation Resistance Test

STP No.: 7

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested:

MS8225 N95

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
j	35	10.5	PASS
2	35	11.0	PASS
3	35	10.3	PASS

Overall Result: PASS

Signature:

6/1/2015

ou Sanical Task Number: TN-20185 Reference No.: CFR 84.180

Inhalation Resistance Test STP No.: 7

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested: MS8225 N95

Comments:

Samples were tested on manometer 000037.

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

Signature:

Sielielie & Retitle

6/1/2015

National Institute for Occupational Safety and Health

Respirator Branch

Test Data Sheet

Task Number: TN-20185

Reference No.: CFR 84.181

Test:

Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested:

MS8225 N95

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	11.4	5.00	0.045	0.054	PASS
2	85	11.3	5.00	0.091	0.099	PASS
3	85	11.1	5.00	0.206	0.212	PASS
4	85	11.3	5.00	0.251	0.262	PASS
5	85	11.1	5.00	0.088	0.095	PASS
6	85	11.8	5.00	0.125	0.125	PASS
7	85	11.7	5.00	0,271	0.300	PASS
8	85	11.8	5.00	0.135	0.135	PASS
9	85	10.3	5.00	0.129	0.133	PASS
10	85	11.2	5.00	0.126	0.128	PASS
11	85	11.7	5.00	0.222	0.222	PASS
12	85	11.2	5.00	0.083	0.086	PASS
13	85	11.8	5.00	0.352	0.352	PASS
14	85	11.4	5.00	0.075	0.085	PASS
15	85	11.7	5.00	0.081	0.082	PASS
16	85	11.2	5.00	0.109	0.112	PASS
17	85	12.3	5.00	0.111	0.123	PASS
18	85	11.5	5.00	0.083	0.083	PASS
19	85	11.0	5.00	0.195	0.195	PASS
20	85	11.9	5.00	0.080	0.080	PASS

Overall Result: PASS

Signature:

6/3/2015 Date:

Task Number: TN-20185 Reference No.: CFR 84.181

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

Manufacturer: Suzhou Sanical Protective Product Manufacturing

Item Tested: MS8225 N95

Comments:

Samples 1-6 were tested on TSI 8130 machine 000191 with sample 6 using timer 000213. Samples 7-8 were tested on TSI 8130 machine 000192. Samples 9-20 were tested on TSI 8130 machine 000193 with samples 19-20 using timer 000215.

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

Signature:

Date:

文化批批

6/3/2015