



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Reference: TN-11948, TN-11950, TN-11952  
Mfr. Reference: SAN0104A, SAN0104C, SAN0104E

Centers for Disease Control  
and Prevention (CDC)  
National Institute for Occupational  
Safety and Health - ALOSH  
1095 Willowdale Road  
Morgantown, WV 26505-2888

Phone: (304) 285-5907  
Fax: (304) 285-6030  
August 1, 2001

Dennis Chien  
San Huei United Company Ltd.  
120 Chi Pei Road, Panchiao City  
Taipei Hsien, Taiwan  
REPUBLIC OF CHINA

Dear Mr. Chien:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your requests dated April 10, 2001. These requests were for approval of the SH9550 N95 filtering facepiece respirator without an exhalation valve, the SH9550C N95 filtering facepiece without an exhalation valve, and the SH9550A N95 filtering facepiece without an exhalation valve.

This request is granted. Approval is granted for English language only on all documentation. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-3713 has been assigned. These respirators are approved for protection at an N95 efficiency particulate level.

The diskette enclosed with this letter contains the final respirator approval labels. The abbreviated labels submitted with the application are accepted as submitted. The cautions and limitations which apply to this approval are on the approval labels. Only those assemblies where 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 labels plus 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.

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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.

Sincerely yours,

A handwritten signature in black ink, appearing to read "R. Metzler", written in a cursive style.

*for* Richard W. Metzler  
Acting Director  
National Personal Protective Technology Laboratory

Enclosures

National Institute for Occupational Safety and Health  
Respirator Branch  
Respirator Certification Team

TEST REPORT

Task Number: TN-11948

Prepared by: Charles Wolfe

Date: July 30, 2001

Manufacturer: San Huei United Company Ltd.

Item Tested: SH9550 N95

Background Information:

On April 10, 2001, San Huei United Company Ltd. requested a new approval for the SH9550 N95 filtering facepiece respirator without an exhalation valve.

Tests Assigned:

A. Exhalation Resistance	84.180
B. Inhalation Resistance	84.180
C. Sodium Chloride N95	84.181

Overall Results:

The items tested passed laboratory testing.

Individual Test Results:

See accompanying test sheets.

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



**Task Number:** TN-11948

**Reference No.:** CFR 84.180

**Test:** Exhalation Resistance Test

**STP No.:** 3

**Manufacturer:** San Huei United Company, Ltd.

**Item Tested:** SH9550 N95

**Filter Type:** Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation		Actual Resistance (MM of H2O) Exhalation		Result
	Initial	Final	Initial	Final	
1	25	0	9.9	0.0	PASS
2	25	0	9.4	0.0	PASS
3	25	0	9.1	0.0	PASS

**Overall Result:** PASS

**Signature:** 

**Date:** 7/30/01

**Engineering Technician**

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



**Task Number:** TN-11948

**Reference No.:** CFR 84.180

**Test:** Inhalation Resistance Test

**STP No.:** 7

**Manufacturer:** San Huei United Company, Ltd.

**Item Tested:** SH9550 N95

**Filter Type:** Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)		Actual Resistance (MM of H2O)		Result
	Inhalation		Inhalation		
	Initial	Final	Initial	Final	
1	35	0	8.4	0.0	PASS
2	35	0	8.1	0.0	PASS
3	35	0	8.1	0.0	PASS

**Overall Result:** PASS

**Signature:** 

**Date:** 7/30/01

**Engineering Technician**

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



**Task Number:** TN-11948

**Reference No.:** CFR 84.181

**Test:** Sodium Chloride (NaCl) - N95

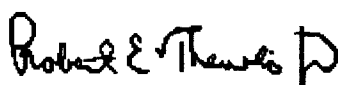
**STP No.:** 59

**Manufacturer:** San Hwei United Company, Ltd.

**Item Tested:** SAN Model SH9550

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.2	5.00	1.06	1.060	PASS
2	85	10.2	5.00	1.49	1.490	PASS
3	85	10.4	5.00	1.19	1.190	PASS
4	85	9.8	5.00	1.31	1.310	PASS
5	85	10.4	5.00	1.4	1.400	PASS
6	85	10.2	5.00	1.31	1.310	PASS
7	85	10.3	5.00	1.33	1.330	PASS
8	85	9.9	5.00	1.15	1.150	PASS
9	85	10.2	5.00	1.32	1.320	PASS
10	85	9.9	5.00	1.33	1.330	PASS
11	85	10.3	5.00	1.2	1.200	PASS
12	85	9.8	5.00	1.33	1.330	PASS
13	85	10.2	5.00	1.14	1.140	PASS
14	85	10.3	5.00	1.21	1.210	PASS
15	85	10.6	5.00	1.37	1.370	PASS
16	85	10.0	5.00	0.934	0.934	PASS
17	85	10.5	5.00	0.977	0.977	PASS
18	85	10.3	5.00	1.05	1.050	PASS
19	85	10.2	5.00	1	1.000	PASS
20	85	9.9	5.00	1.12	1.120	PASS

**Overall Result:** PASS

**Signature:** 

**Date:** 7/3/01

**Engineering Technician**

National Institute for Occupational Safety and Health  
Respirator Branch  
Respirator Certification Team

TEST REPORT

Task Number: TN-11950

Prepared by: Charles Wolfe

Date: July 30, 2001

Manufacturer: San Hwei United Company Ltd.

Item Tested: SH9550C N95

Background Information:

On April 10, 2001, San Hwei United Company Ltd. requested a new approval for the SH9550C N95 filtering facepiece respirator without an exhalation valve.

Tests Assigned:

A. Exhalation Resistance	84.180
B. Inhalation Resistance	84.180

Overall Results:

The items tested passed laboratory testing.

Individual Test Results:

See accompanying test sheets.

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



**Task Number:** TN-11950

**Reference No.:** CFR 84.180

**Test:** Exhalation Resistance Test

**STP No.:** 3

**Manufacturer:** San Huei United Company, Ltd.

**Item Tested:** SH9550C N95

**Filter Type:** Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation		Actual Resistance (MM of H2O) Exhalation		Result
	Initial	Final	Initial	Final	
1	25		12.7		PASS
2	25	0	12.7	0.0	PASS
3	25	0	12.7	0.0	PASS

**Overall Result:** PASS

**Signature:**

A handwritten signature in black ink, appearing to read "Charles S. A. Wolfe". The signature is written in a cursive, flowing style.

**Date:** 7/30/01

**Engineering Technician**



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



**Task Number:** TN-11950

**Reference No.:** CFR 84.180

**Test:** Inhalation Resistance Test

**STP No.:** 7

**Manufacturer:** San Huei United Company, Ltd.

**Item Tested:** SH9550C N95

**Filter Type:** Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)		Actual Resistance (MM of H2O)		Result
	Inhalation		Inhalation		
	Initial	Final	Initial	Final	
1	35	0	11.4	0.0	PASS
2	35	0	11.4	0.0	PASS
3	35	0	11.4	0.0	PASS

**Overall Result:** PASS

**Signature:**

A handwritten signature in black ink, appearing to read "Charles S. A. Wolfe". The signature is written in a cursive, flowing style.

**Date:** 7/30/01

**Engineering Technician**