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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,



**William A. Hoffman  
Acting Chief  
Technology Evaluation Branch  
National Personal Protective Technology Laboratory**

**Enclosures**

National Institute for Occupational Safety and Health  
Technology Evaluation Branch  
Certification, Evaluation, and Testing Section

**TEST REPORT**

Task Number: TN-14412

Prepared by: Jeremy Brannen

Date: March 17, 2006

Manufacturer: San Huei United Company, Ltd.

Item Tested: SH3500

**Background Information:**

In an application dated February 24, 2006 San Huei United Company requested an approval of the model SH3500 N95 filtering facepiece respirator.

**Tests Assigned:**

A. Exhalation Resistance Test	84.180
B. Inhalation Resistance Test	84.180
C. Sodium Chloride (NaCl) – 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-14412

**Reference No.:** CFR 84.181

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

**STP No.:** 59

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

**Item Tested:** SH3500

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	8.2	5.00	0.948	0.948	PASS
2	85	9.1	5.00	0.710	0.710	PASS
3	85	8.7	5.00	1.050	1.050	PASS
4	85	12.0	5.00	0.077	0.077	PASS
5	85	9.3	5.00	0.976	0.976	PASS
6	85	12.7	5.00	1.730	1.730	PASS
7	85	8.3	5.00	1.020	1.020	PASS
8	85	9.3	5.00	0.842	0.842	PASS
9	85	8.9	5.00	0.930	0.930	PASS
10	85	12.7	5.00	0.081	0.081	PASS
11	85	9.0	5.00	0.865	0.865	PASS
12	85	9.5	5.00	0.781	0.781	PASS
13	85	9.5	5.00	1.140	1.140	PASS
14	85	9.8	5.00	1.010	1.010	PASS
15	85	9.0	5.00	0.825	0.825	PASS
16	85	8.4	5.00	0.669	0.669	PASS
17	85	8.7	5.00	0.716	0.716	PASS
18	85	9.0	5.00	0.774	0.787	PASS
19	85	12.6	5.00	0.091	0.091	PASS
20	85	9.3	5.00	1.000	1.000	PASS

**Overall Result:** PASS

**Signature:**

*Jana Jensen*

**Engineering Technician**

**Date:** 3/17/2006

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



**Task Number:** TN-14412

**Reference No.:** CFR 84.180

**Test:** Exhalation Resistance Test

**STP No.:** 3

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

**Item Tested:** SH3500

**Filter Type:** Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	10.2	PASS
2	25	9.7	PASS
3	25	10.2	PASS

**Overall Result:** PASS

**Signature:**

A handwritten signature in cursive script, reading "Laura J. Jumper".

**Engineering Technician**

**Date:** 3/17/2006



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



**Task Number:** TN-14412

**Reference No.:** CFR 84.180

**Test:** Inhalation Resistance Test

**STP No.:** 7

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

**Item Tested:** SH3500

**Filter Type:** Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	12.7	PASS
2	35	9.7	PASS
3	35	10.9	PASS

**Overall Result:** PASS

**Signature:**

A handwritten signature in cursive script, appearing to read "Janna Jensen".

**Engineering Technician**

**Date:** 3/17/2006



# SAN HUEI UNITED CO., LTD

ISO-9001 & ISO-14001 Certified Manufacturer Your Best Partner in Respiratory Protection

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## SH3500 SERIES NIOSH N95 APPROVED RESPIRATORS

**1. Item No. :** SH3500 N95 Particulate Respirator.

**2. Standards :** Federal Register 42 CFR Part 84, as class N95.

### 3. Applications :

N95 disposable particulate respirators are approved with filtration 95% effective against particulate aerosols free of oils. Conforms to NIOSH 42 CFR Part 84 standard as N95 class.

Recommended applications : textile industry, craft work, iron and steel industry, mining, underground civil engineering and woodworking, hospital, laboratory, and disease control ...etc.

N95 respirators can provide protection against particulate aerosols free of oils containing the following materials such as : china clay, cement, cellulose, sulfur, cotton, flour, carbon, ferrous metals, hard wood, coal, iron ore, aluminum, bacteria and mycobacterium tuberculosis (T.B.).

### 4. Product Description :

SH3500 series particulate respirators are NIOSH N95 certified single-use disposable respirators with NIOSH approval according to U.S. Federal Register 42 CFR Part 84.

Manufacturer : San Huei United Co., Ltd. with ISO-9001 and ISO-14001 certification which are both issued by BSI (British Standards Institution).

#### 4.1 SH3500 N95 Particulate Respirator (NIOSH Approval No. TC-84A-4313)

N95 : filtration 95% effective against particulate aerosols free of oils.

### 5. Material :

- 5.1 Outer Layer : Polypropylene.
- 5.2 Filter Media : Melt-Blown (Polypropylene).
- 5.3 Inner Layer : Polypropylene.
- 5.4 Nose Piece : PE Encapsulated Iron Wire.
- 5.5 Headband : Latex-Free Cloth Headstrap (synthetic rubber thread and polyester yarn).
- 5.6 Headband Buckle : Polypropylene.

### 6. Dimension :

- 6.1 Respirator :  
Width : 114 mm.  
Height : 159 mm.
- 6.2 Nose Piece : 90 X 5.5 X 1.3 mm (LxWxT).
- 6.3 Headband :  
Loop Headband : 700 X 4.5 X 1 mm (LxWxT).





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Reference: TN-14412  
Mfr. Reference: SAN0602A

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and Prevention (CDC)  
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March 29, 2006

INSTOCKING LLC

Mr. Dennis Chien  
San Huei United Co., LTD  
120 Chi Pei Road  
Panchiao  
Taipei Hsein, 220 Taiwan, Republic of China

Dear Mr. Chien:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated February 24, 2006. This request was for an approval of the model SH3500 N95 filtering facepiece respirator.

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-4313 has been assigned. The respirator is approved for protection at a N95 particulate efficiency level.

The diskette 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 assemblies consist of the parts as listed on the approval labels 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.