



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-21694
Mfr. Reference: RIZSQ100CVb

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

May 16, 2018

Na Jiao
Product Development Dept. Manager
Rizhao Sanqi Medical & Health Articles Co., Ltd
Heshan International Industrial Park
Rizhao City, Shangdong Province, 276800
CHINA

Dear Na Jiao:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted August 1, 2017. This request was for approval of the model SQ100CVb, air-purifying filtering-facepiece respirator with exhalation valve for protections against particulates at N95 filter efficiency level. The complete respirator configuration is detailed on assembly matrix, file name *SQ100CVbAMa.xls*, revision A, dated: July 2, 2017.

The site qualification was conducted at your facility in Rizhao City, Shangdong, China on January 8, 2018, and your responses to the Corrective Action Requests (CARs), specifically CARs 21694-01 through 21694-05 have been accepted and all the nonconformance issues related to the site qualification have been resolved.

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 to be produced in languages other than English. Approval number TC-84A-8086 has been assigned. This respirator is approved for protection against particulates at 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 final respirator approval label is included as an attachment to this letter. 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).

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,

A handwritten signature in blue ink, appearing to read 'Jeffrey Peterson', with a long horizontal flourish extending to the right.

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures

	National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory Evaluation and Testing Branch
---	--

TEST REPORT

Task Number: TN-21694

Manufacturer: Rizhao Sanqi Medical & Health Articles Co., Ltd.

Prepared by: Nichole Petitta

Date: September 20, 2017

Tests Conducted by: Emily Merkle, Nichole Petitta

Respirator Tested: SQ100CVb

Background Information

Respirator tested as per test request.

Tests Assigned

<u>Test Description</u>	<u>STP Number</u>
A. Exhalation Resistance Test	TEB-APR-STP-0003
B. Exhalation Valve Leakage Test	TEB-APR-STP-0004
C. Inhalation Resistance Test	TEB-APR-STP-0007
D. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested did meet the requirements of all the above procedures.

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



Task Number: TN-21671

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Shining Star Electronic Technology Co., Ltd

Filter Type: Filter Only

Item Tested: SS9001V-N95

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	6.1	PASS
2	25	5.9	PASS
3	25	6.0	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000282.

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



Yes



No

Signature:

Nichole L. Petitta

Date: 8/17/2017

Engineering Technician

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



Task Number: TN-21671 **Reference No.:** CFR 84.182
Test: Exhalation Valve Leakage Test **STP No.:** 4
Manufacturer: Shining Star Electronic Technology Co., Ltd
Item Tested: Exhalation Valve

LEAKAGE						
Sample	Trial #1 (mL/min.)	Trial #2 (mL/min.)	Trial #3 (mL/min.)	Average (mL/min.)	Maximum Allowable (mL/min.)	Result
Valve 1	1.88	1.78	1.78	1.81	30.00	PASS
Valve 2	2.52	2.50	2.50	2.51	30.00	PASS
Valve 3	3.44	3.41	3.39	3.41	30.00	PASS
Overall Result: PASS						

Signature:

A handwritten signature in black ink that reads "Emily M. Merkle". The signature is written in a cursive, flowing style.

Engineering Technician

Date: 8/29/2017

Task Number: TN-21671

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

Manufacturer: Shining Star Electronic Technology Co., Ltd

Item Tested: Exhalation Valve

Comments:

Samples 1-3 were tested using Manometer 000297 and Gilibrator 000041.

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

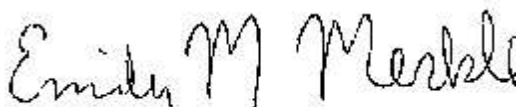


Yes



No

Signature:



Engineering Technician

Date: 8/29/2017

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



Task Number: TN-21671

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Shining Star Electronic Technology Co., Ltd

Item Tested: SS9001V-N95

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	7.3	PASS
2	35	8.1	PASS
3	35	8.0	PASS
Overall Result: PASS			

Signature:

Nichole L. Petitta

Date: 8/17/2017

Engineering Technician

Task Number: TN-21671

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Shining Star Electronic Technology Co., Ltd

Item Tested: SS9001V-N95

Comments:

Samples were tested on manometer 000286.

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



Yes



No

Signature:

Nichole L. Petitta

Date: 8/17/2017

Engineering Technician

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



Task Number: TN-21671

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Shining Star Electronic Technology Co., Ltd

Item Tested: SS9001V-N95

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.0	5.00	0.374	0.497	PASS
2	85	9.9	5.00	0.616	0.684	PASS
3	85	9.5	5.00	0.454	0.601	PASS
4	85	9.0	5.00	0.342	0.449	PASS
5	85	9.5	5.00	0.337	0.464	PASS
6	85	9.7	5.00	0.233	0.384	PASS
7	85	9.3	5.00	0.466	0.613	PASS
8	85	10.0	5.00	0.330	0.455	PASS
9	85	8.6	5.00	0.439	0.640	PASS
10	85	9.8	5.00	0.606	0.774	PASS
11	85	8.7	5.00	0.602	0.763	PASS
12	85	9.7	5.00	0.802	0.802	PASS
13	85	9.2	5.00	0.770	0.971	PASS
14	85	10.1	5.00	1.040	1.040	PASS
15	85	9.2	5.00	0.446	0.629	PASS
16	85	9.3	5.00	0.478	0.633	PASS
17	85	9.2	5.00	0.472	0.611	PASS
18	85	9.1	5.00	0.442	0.555	PASS
19	85	9.1	5.00	0.468	0.612	PASS
20	85	9.3	5.00	0.510	0.644	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 8/31/2017

Engineering Technician

Task Number: TN-21671

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Shining Star Electronic Technology Co., Ltd

Item Tested: SS9001V-N95

Comments:

Samples 1-8 were tested on TSI 8130 machine 000332 using timer 000213. Samples 9-13 were tested on TSI 8130 machine 000333 using timer. Samples 14-20 were tested on TSI 8130 machine 000334 using timer 000215.

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



Yes



No

Signature:

Nichole L. Petetta

Date: 8/31/2017

Engineering Technician