



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-22387
Mfr. Reference: RIZSQ100Vc

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
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September 13, 2018

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

Dear Na Jiao:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted June 18, 2018. This request was for approval of the model SQ100Vb 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 *SQ100VbAMa.xls*, revision A, dated September 9, 2017.

All associated testing including the sodium chloride (NaCl) particulate testing for the model SQ100Cb respirator, was successfully conducted under TN-21868, and was reported at the conclusion of that project.

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-8111 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

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,

Collin Miller

for 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
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TEST REPORT

Task Number: TN-21868

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

Prepared by: Nichole Petitta

Date: November 10, 2017

Tests Conducted by: Nichole Petitta

Respirator Tested: SQ100Vb

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 established performance requirements.

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



Task Number: TN-21868

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

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

Filter Type: Filter Only

Item Tested: SQ100Vb

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	5.2	PASS
2	25	5.2	PASS
3	25	4.7	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: 11/6/2017

Engineering Technician

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



Task Number: TN-21868

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

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

Item Tested: SQ100Vb

LEAKAGE						
Sample	Trial #1 (mL/min.)	Trial #2 (mL/min.)	Trial #3 (mL/min.)	Average (mL/min.)	Maximum Allowable (mL/min.)	Result
Valve 1	18.07	18.16	18.15	18.13	30.00	PASS
Valve 2	0.00	0.00	0.00	0.00	30.00	PASS
Valve 3	8.78	8.64	8.57	8.66	30.00	PASS
Overall Result: PASS						

Signature:

A handwritten signature in black ink that reads "Nicholas L. Petitta".

Date: 11/8/2017

Engineering Technician

Task Number: TN-21868

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

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

Item Tested: SQ100Vb

Comments:

Samples were tested on Gilibrator 000041.

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



Yes



No

Signature:

Nichole L. Petitta

Date: 11/8/2017

Engineering Technician

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



Task Number: TN-21868

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

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

Item Tested: SQ100Vb

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	9.1	PASS
2	35	8.4	PASS
3	35	8.3	PASS
Overall Result: PASS			

Signature:

Nichole L. Petitta

Date: 11/6/2017

Engineering Technician

Task Number: TN-21868

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

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

Item Tested: SQ100Vb

Comments:

Samples were tested on manometer 000286.

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

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Yes

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No

Signature:

Nichole L. Petitta

Date: 11/6/2017

Engineering Technician

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



Task Number: TN-21868

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

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

Item Tested: SQ100Vb

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	9.5	5.00	1.030	1.030	PASS
2	85	9.3	5.00	0.610	0.610	PASS
3	85	10.1	5.00	0.974	0.974	PASS
4	85	10.0	5.00	1.040	1.040	PASS
5	85	9.7	5.00	1.140	1.140	PASS
6	85	10.1	5.00	1.340	1.340	PASS
7	85	10.2	5.00	0.719	0.719	PASS
8	85	9.9	5.00	0.770	0.770	PASS
9	85	9.7	5.00	0.902	0.931	PASS
10	85	9.5	5.00	0.739	0.739	PASS
11	85	9.6	5.00	0.736	0.736	PASS
12	85	9.8	5.00	1.850	1.900	PASS
13	85	10.4	5.00	0.874	0.874	PASS
14	85	10.1	5.00	0.842	0.842	PASS
15	85	10.2	5.00	0.747	0.747	PASS
16	85	9.6	5.00	0.868	0.868	PASS
17	85	9.7	5.00	1.470	1.470	PASS
18	85	9.7	5.00	0.615	0.615	PASS
19	85	9.9	5.00	0.736	0.736	PASS
20	85	10.3	5.00	0.835	0.835	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 11/10/2017

Engineering Technician

Task Number: TN-21868

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

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

Item Tested: SQ100Vb

Comments:

Samples 1-8 were tested on TSI 8130 machine 000332. Samples 9-11 were tested on TSI 8130 machine 000333 using timer 000214. Samples 12-20 were tested on TSI 8130 machine 000334.

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



Yes



No

Signature:

Nichole L. Petitta

Date: 11/10/2017

Engineering Technician