

FICHA TÉCNICA DEL PRODUCTO

MASCARILLA DESECHABLE N-95 SIN VÁLVULA

DESCRIPCIÓN:

La mascarilla desechable N-95 sin válvula brinda una efectiva, confortable e higiénica protección respiratoria contra partículas sólidas y líquidos no oleosos. Su diseño con bandas elásticas, espuma de sellado y el clip de aluminio para el ajuste a la nariz aseguran un excelente sello adaptándose a un amplio rango de tamaños de cara.



Bandas metálica para excelente ajuste y máximo confort en el tabique nasal.

Excepcional filtro interior para una baja resistencia a la inhalación y exhalación.

Bandas elásticas para la cabeza selladas ultrasónicamente para mejor firmeza.

Banda nasal suave, cómoda para el trabajador.

VISTA INTERIOR



Imagen Referencial



Certificación CE
Mascarilla respirador FFP2 con certificado CE en cumplimiento de la Directiva EU 2016/425 de acuerdo al test estándar EN149:2001+A1:2009.



CERTIFICACIÓN



Makrite Industries, Inc.
11F-5, No. 79, SEC 1, Hsin Tai Wu Rd.
His-Chih, Taipei Hsein, Taiwan, R.O.C.
Telephone: (02)2698-2419



This respirator is only approved in the following configuration:

TC	Protection ¹	Respirator	Cautions and Limitations ²
		9500	
84A-3323	N95	X	ABCJMNOP

1. Protection

N95 - Particulate Filter
(95% filter efficiency level)
effective against
particulate aerosols free of
oil; Time use restrictions
may apply.

2. Cautions and Limitations

- A - Not for use in atmospheres containing less than 19.5% oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do Not exceed maximum use concentrations established by regulatory standards.
- J - Failure to properly use and maintain this product could result in injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to users instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.

CERTIFICACIÓN



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Reference: TN-17685
Mfr. Reference: MAK-1105

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

April 19, 2011

Mr. Alexander Freedman, President
Makrite Industries Inc.
236 Upland Avenue
Newton Highlands, Massachusetts 02461-2003

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 8, 2011. This request was for an approval of the model 9500-N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAK1105AM1.xls.

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. The approval number TC-84A-5411 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level (N95).

The CD enclosed with this letter contains the final respirator 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).

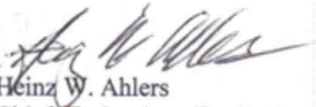
This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

CERTIFICACIÓN

Page 2 – Mr. Alexander Freedman – TN-17685

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,



Heinz W. Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

CERTIFICACIÓN



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 18070
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-17685

Manufacturer: Makrite Industries, Inc.

Prepared by: Jeremy Brannen

Tests Conducted by: Jeremy Brannen

Date: March 30, 2011

Respirator Tested: 9500-N95

Background Information

In an application accepted March 8, 2011 Makrite Industries requested an approval of the model 9500-N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAK1105AM1.xls.

Tests Assigned

<u>Test Description</u>	<u>STP Number</u>	<u>Reference</u>
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See attached test data sheets.

CERTIFICACIÓN

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



Task Number: TN-17685

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Makrite Industries, Inc.

Filter Type: Filter Only

Item Tested: 9500-N95

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Exhalation	Exhalation	
1	25	5.6	PASS
2	25	5.3	PASS
3	25	5.6	PASS

Overall Result: PASS

Comments:

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

Yes No

Signature:



Engineering Technician

Date: 3/30/2011

CERTIFICACIÓN

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



Task Number: TN-17685
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: 9500-N95

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Inhalation	Inhalation	
1	35	6.9	PASS
2	35	6.9	PASS
3	35	6.9	PASS
Overall Result: PASS			

Signature:



Engineering Technician

Date: 3/30/2011

CERTIFICACIÓN

Task Number: TN-17685
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: 9500-N95

Reference No.: CFR 84.180
STP No.: 7

Comments:

Was all equipment verified to be in calibration throughout all testing? Yes No

Signature:



Engineering Technician

Date: 3/30/2011

CERTIFICACIÓN

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



Task Number: TN-17685

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Makrite Industries, Inc.

Item Tested: 9500-N95

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	7.8	5.00	0.373	0.426	PASS
2	85	7.9	5.00	0.375	0.426	PASS
3	85	7.4	5.00	0.777	0.976	PASS
4	85	8.0	5.00	0.568	0.784	PASS
5	85	8.2	5.00	0.605	0.831	PASS
6	85	7.7	5.00	0.684	0.885	PASS
7	85	7.4	5.00	0.724	0.957	PASS
8	85	8.4	5.00	0.346	0.569	PASS
9	85	7.4	5.00	0.281	0.481	PASS
10	85	8.2	5.00	0.293	0.556	PASS
11	85	8.4	5.00	0.543	0.623	PASS
12	85	7.9	5.00	0.643	0.763	PASS
13	85	8.0	5.00	0.738	0.845	PASS
14	85	8.0	5.00	0.516	0.624	PASS
15	85	7.8	5.00	0.548	0.632	PASS
16	85	7.6	5.00	0.726	0.961	PASS
17	85	7.9	5.00	0.536	0.597	PASS
18	85	8.5	5.00	0.555	0.667	PASS
19	85	8.4	5.00	0.842	0.992	PASS
20	85	7.8	5.00	0.743	0.861	PASS

Overall Result: PASS

Signature:



Engineering Technician

Date: 3/30/2011

CERTIFICACIÓN

Task Number: TN-17685

Test: Sodium Chloride (NaCl) - N95

Manufacturer: Makrite Industries, Inc.

Item Tested: 9500-N95

Reference No.: CFR 84.181

STP No.: 59

Comments:

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

Yes No

Signature:



Engineering Technician

Date: 3/30/2011