

FICHA TÉCNICA

Respirador (mascarilla) **N95**
Certificación **Niosh**

Mascarilla en forma de copa, uso
para personal médico .

Marca
Modelo

Benehal
MS6115L



 /ladespensacr

 @ladespensacr

CARACTERÍSTICAS



- Clip de aluminio para el ajuste a la nariz que sirve de sello eficaz a un amplio rango de tamaños de cara.
- No irritante, respiración más fácil.
- Eco amigable, respetuoso del medio ambiente.
- Suave y ligero.
- Cómodo de llevar, fácil de usar.
- Sus bandas elásticas de excelente calidad permiten un ajuste efectivo y confortable.
- Tela no tejida de Polipropileno y Poliéster.
- Certificado aprobado por NIOSH (National Institute for Occupational Safety and Health) de Estados Unidos, bajo la Norma 42 CFR Parte 84. Aprobación TC-84A-5037.
- 5 capas
- Color blanca
- Dimensiones: 135*125*200mm
- Empaque: 20 mascarillas por caja. 400 unds por saco



La  espensacr

La Despensacr

La Despensa tiene procesos de calidad muy estrictos con los fabricantes. Trabajamos como aliados comerciales de DHL, en donde ellos nos ofrecen un producto en el cual primero se visita la fábrica para inspeccionar que el lote a comprar corresponda al mismo cotizado y reúne toda la documentación inclusive antes de sacarlo de la fábrica para corroborar con Aduanas en China y el Ministerio de Salud de este país que toda la documentación y certificaciones sean correctas. A continuación muestra de certificación Europea CE y Norteamericanos FDA, por lo que la calidad está garantizada.

 DEPARTMENT OF HEALTH & HUMAN SERVICES **FILE COPY** Public Health Service

NIOSH Reference: TN-10278
MSA Reference: SSPMS-113a

Center for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P-2, Box 18075
Pittsburgh, PA 15260-0075
Phone: 412-398-4000
Fax: 412-398-4001
January 31, 2012

Guoping Jiang, Technical Director
Suzhou Sanical Protective Product Manufacturing Co., Ltd.
No. 6, Xibenggang Street, Yangchengfu Town
Xiangcheng District
Suzhou City, 215002
China

Dear Guoping Jiang:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted December 16, 2011. This request was for approval of the models MS6115 filtering facepiece air purifying respirators (APR), part numbers SC-MS6117 and SC-MS6118L, for protection against particulates at a N95 filter efficiency level, reference assembly matrix MS6115AMS, etc. In addition, the Suzhou Sanical Protective Product Manufacturing Company Quality Manual, document number SC-QM-2011, revision A-0 and effective date 2011-05-11 was presented for review.

This request is granted. Approval is 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-843, 0130 has been assigned. These respirators are approved for protection against particulates at a 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 84.43(a) and, on the basis of this review, this quality manual is accepted.

The CD enclosed with this letter contains the final respirators approval label. The abbreviated labels have 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 whose new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

Page 2 - Guoping Jiang - TN-10278

The approved assemblies consist 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 labels 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 respirators by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that these respirators have met the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).

No changes may be made to any respirator 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,

Heino W. Alden
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 37070
Pittsburgh, PA 15250

TEST REPORT

Task Number: TN-18228

Manufacturer: Suzhou Sanical Protective Product Manufacturing Co., LTD

Prepared by: Jeremy Brannon

Tests Conducted by: Jeremy Brannon / Keith Fisher

Date: January 11, 2012

Respirator Tested: SC-MS6115/SC-MS6116L

Background Information

In an application accepted December 30, 2011 Suzhou Sanical Protective Product Manufacturing requested approvals of the models MS6115 filtering facepiece air purifying respirator (APR), part numbers SC-MS6115 and SC-MS6116L, for protection against particulates at a 30% filter efficiency level, reference assembly points MS6115AM1 via. In addition, the Suzhou Sanical Protective Product Manufacturing Company Quality Manual, document number SC-QM-2011, revision A0 and effective date 2011-01-13 was presented for review.

Tests Anticipated

Test Description	STP Number	Reference
A. Exhalation Resistance Test	RCT-APR-STP-0005	\$4, 180
B. Inhalation Resistance Test	TRB-APR-STP-0007	\$4, 180
C. Sodium Chloride (NaCl) MIST Test	TRB-APR-STP-0009	\$4, 181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See the attached test data sheets.

National Institute for Occupational Safety and Health
Respirator Branch



Test Data Sheet

Task Number: TN-18228 Reference No.: CTR 01-201
Test: Inhalation Resistance Test STP No.: 7
Manufacturer: Suzhou Sanical Protective Product Manufacturing

Filter Type: Filter Only

Item Tested: SC-MS6115/SC-MS6116L

Sample	Maximum Allowable Resistance (MM of H ₂ O)		Result
	Inhalation	Exhalation	
1	25	12.8	PASS
2	25	12.1	PASS
3	25	12.4	PASS
4	25	11.8	PASS
5	25	12.2	PASS
6	25	11.8	PASS

Overall Results: PASS

Comments:
Samples 1-3 were tested using the SC-MS6115, and samples 4-6 were tested using the SC-MS6116L.
Was all equipment verified to be in calibration throughout all testing? Yes No

Signature: Date: 11/11/2012
Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch



Test Data Sheet

Task Number: TN-18228 Reference No.: CTR 01-201
Test: Inhalation Resistance Test STP No.: 7
Manufacturer: Suzhou Sanical Protective Product Manufacturing
Item Tested: SC-MS6115/SC-MS6116L

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H ₂ O)		Result
	Inhalation	Exhalation	
1	30	12.7	PASS
2	30	12.7	PASS
3	30	10.0	PASS
4	30	10.9	PASS
5	30	11.8	PASS
6	30	11.9	PASS

Overall Results: PASS

Signature: Date: 11/11/2012
Engineering Technician

Task Number: TN-18228 Reference No.: CTR 01-201
Test: Inhalation Resistance Test STP No.: 7
Manufacturer: Suzhou Sanical Protective Product Manufacturing
Item Tested: SC-MS6115/SC-MS6116L

Comments:
Samples 1-3 were tested using the SC-MS6115, and samples 4-6 were tested using the SC-MS6116L.
Was all equipment verified to be in calibration throughout all testing? Yes No

Signature: Date: 11/11/2012
Engineering Technician

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



Task Number: TN-18228 Release No: (TR 84 10)
 Test: Sodium Chloride (NaCl) - 100 EEP No: 20
 Manufacturer: Sulzer Surgical Products Medical Manufacturing
 Test Model: SC-826113

Fiber	Flow Rate	Actual Filter Efficiency	Maximum Allowable Percent Leakage	Initial Percent Leakage	Minimum Percent Leakage	Result
1	95	14.2	0.00	0.917	0.919	PASS
2	95	14.4	0.00	0.909	0.909	PASS
3	95	14.0	0.00	0.940	0.940	PASS
4	95	14.2	0.00	0.820	0.820	PASS
5	95	14.0	0.00	0.817	0.817	PASS
6	95	14.0	0.00	1.130	1.130	PASS
7	95	14.0	0.00	0.960	0.960	PASS
8	95	14.1	0.00	0.814	0.814	PASS
9	95	14.0	0.00	0.700	0.700	PASS
10	95	14.0	0.00	0.856	0.856	PASS
11	95	14.0	0.00	0.870	0.870	PASS
12	95	14.0	0.00	1.226	1.226	PASS
13	95	14.0	0.00	0.787	0.787	PASS
14	95	14.0	0.00	1.051	1.051	PASS
15	95	13.9	0.00	1.986	1.986	PASS
16	95	13.7	0.00	0.870	0.870	PASS
17	95	14.4	0.00	0.780	0.780	PASS
18	95	13.4	0.00	0.479	0.479	PASS
19	95	14.0	0.00	0.800	0.800	PASS
20	95	14.0	0.00	0.889	0.889	PASS

Overall Result: PASS

Signature: Date: 01/10/2012
 Engineering Technician

Task Number: TN-18228 Release No: (TR 84 10)
 Test: Sodium Chloride (NaCl) - 100 EEP No: 20
 Manufacturer: Sulzer Surgical Products Medical Manufacturing
 Test Model: SC-826113

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

Signature: Date: 01/10/2012
 Engineering Technician

Approval - Concurrence

Concurrence - Process in order shown, sending the project to the next person on the list.
 TN18228 (SAP)

Author - Be sure to complete the checklist to include all relevant information for the Program Assistant

Author: Date sent to peer review and MIRA (if applicable): 1/10/2012

Branch representative: Date sent to Secretary: N/A

Concurrence Approval: Date sent to Branch Chief (or Secretary): 1/10/2012

Branch Chief: Date sent to Secretary: 1/10/2012

Secretary: Date ready for signature: 1/10/2012

Secretary: Date mailed: 1/10/2012

Lucinski, Lillian (CDC/NIOSH/NPPTL)

From: Adams, Helen W. (CDC/NIOSH/NPPTL)
 Sent: Monday, January 30, 2012 3:48 PM
 To: Lucinski, Lillian (CDC/NIOSH/NPPTL); Peterson, Jeff (CDC/NIOSH/NPPTL); Pouchot, Thomas D. (CDC/NIOSH/NPPTL); Thornton, Terry L. (CDC/NIOSH/NPPTL)
 Subject: FW: TN18228SAPnew.doc; TN18228 Approval Letter
 Attachments: 18228 Concurrence and checklist.xls; TN18228SAPnew.doc; 18228rep.doc

I concur

-----Original Message-----

From: Thornton, Terry L. (CDC/NIOSH/NPPTL)
 Sent: Friday, January 27, 2012 8:00 AM
 To: Adams, Helen W. (CDC/NIOSH/NPPTL)
 Cc: Lucinski, Lillian (CDC/NIOSH/NPPTL); Harvey, Karen (CDC/NIOSH/NPPTL)
 Subject: FW: TN18228SAPnew.doc; TN18228 Approval Letter

Approved and forwarded for your signature. 08

-----Original Message-----

From: Pouchot, Thomas D. (CDC/NIOSH/NPPTL)
 Sent: Thursday, January 26, 2012 2:57 PM
 To: Thornton, Terry L. (CDC/NIOSH/NPPTL)
 Subject: TN18228SAPnew.doc; TN18228 Approval Letter

Terry,

Attached are the approval letter, test report and concurrence checklist for TN18228 (SAP). The file will be in your office shortly.

Any issues please contact me.

Tom Pouchot
 Ext 4036

The message is ready to be sent with the following file or link attachments:

TN18228SAPnew.doc
 18228Concurrence and checklist.xls
 18228rep.doc

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.



Fiscal Year 2021

CERTIFICATE OF FDA REGISTRATION

This certifies that: **Suzhou Sanical Protective Product Manufacturing Co., Ltd**
No.21, Xihenggang Street, Yangchenghu Town, Xiangcheng
District,Suzhou, Jiangsu, 215138,CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through from a 3rd party registrant.

Owner/Operator Number: 10079658

Device Listing#:

Listing No.	Code:	Proprietary Name:	Activities:
D429937	MSH	Surgical Respirator- N95 mask	Manufacturer

will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. 3rd party registrant makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder; for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate holder's device or establishment by the U.S. Food and Drug Administration. 3rd party registrant assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.20, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration, U/3rd party registrant is not affiliated with the U.S. Food and Drug Administration.

U.S. Agent

Contact Name: Ziyu Lu

Address: 8934 Gettysburg St Bellrose, NY 11426 U.S.A

Phone: 1-846-2230128

E-mail: ada-agent@h-kun.cn



Issued Date: Dec 21, 2020

Expiration Date: December 31, 2021

Descargo de responsabilidad: La Despensa considera que la información en esta ficha de datos técnicos es precisa y representa la mejor y más actualizada información disponible para nosotros. La Despensa no hace representaciones o garantías expresas o implícitas, con respecto a la idoneidad del material para cualquier propósito o la exactitud de la información contenida en este documento. En consecuencia, el material de La Despensa no será responsable de los daños resultantes del uso o la dependencia de esta información.



**JUNTOS LE GANAREMOS
AL VIRUS**

La **D**espensacr