

RESPIRADOR N95

Dasheng
Modelo: DTC3X

**BANDAS ELÁSTICAS
PARA LA CABEZA**

**AJUSTE NASAL
INTERNO**

**PROTECCIÓN
CONTRA VIRUS**

DESCRIPCIÓN:

Respirador diseñado con el fin de lograr una mayor comodidad al mismo tiempo una efectiva protección al usuario, tanto en su colocación y respiración. Su forma convexa y diseño aseguran un excelente sello, adaptándose a un amplio rango de tamaños de cara.

El respirador de libre de mantenimiento brinda una efectiva y confortable protección respiratoria contra partículas sólidas y líquidas sin aceite.

CARACTERÍSTICAS:

- Diseño ultraliviano y ergonómico.
- Tela no tejida en Poliuretano-poliéster.
- Hebillas termo-selladas.
- Elástico doble para mejor ajuste.
- Material filtrante de color blanco.

FORMA DE USO:



PRECAUCIONES:

No usar cuando las concentraciones sean mayores a 10 veces el límite de exposición. No usar en atmósferas en las que el contaminante esté en concentraciones IDLH (Inmediatamente Peligroso para la Vida y la Salud).

No usar en atmósferas que contengan vapores y gases tóxicos, asbestos o polvo proveniente de lavado con Chorro de arena, en exposición directa.

Coloque el respirador sobre su boca y nariz con ajuste metálico hacia arriba. Tire el elástico por detrás de su cabeza. Presione el ajuste metálico para una mayor firmeza y comodidad.

CERTIFICACIÓN NIOSH N95 -USA NORMA 42CFR84

Av. Roca y Coronado entre 2do. y 3er. anillo

HERRACRUZ
Innovación & Tecnología

LP: +591 715 66108
CBBA: +591 694 73570

SCZ: +591 691 57075
+591 773 00666
+591 691 27056



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Reference: TN-14513

Mfr. Reference: SDHDTC3XAF-2

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
July 20, 2006

Ms. Maggie Zhong
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Room 604, No. 7 Building
No.20 Handan Road
Shanghai, 200437
CHINA

Dear Ms. Zhong:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 15, 2006. This request was for approval of the model DTC3X N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Dasheng Health Products Manufacture Co. Quality Manual, Edition B, dated May 10, 2003.

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-4329 has been assigned. The respirator is approved for protection at a N95 particulate efficiency level.

NIOSH has also reviewed the quality manual presented and finds that it meets or exceeds the minimum technical requirements for quality assurance plans outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and on the bases of this review an approval is granted for this quality manual.

The CD 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 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.

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.

A copy of the quality manual will be retained by NIOSH and incorporated into our files. Any future changes to this approved quality manual must be submitted to NIOSH for a modification of this approval.

Sincerely yours,



Heinz W. Ahlers
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-14513

Prepared by: Jeremy Brannen

Date: July 14, 2006

Manufacturer: Shanghai Dasheng Health Products Manufacture Company

Item Tested: DTC3X

Background Information:

In an application dated May 15, 2006 Shanghai Dasheng Health Products Manufacture Company requested an approval of the model DTC3X N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Dasheng Health Products Manufacture Co. Quality Manual, Edition B, dated May 10, 2003.

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-14513

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Shanghai Dasheng Health Products Manufacture

Item Tested: DTC3X

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	8.6	5.00	0.254	0.258	PASS
2	85	9.0	5.00	0.163	0.164	PASS
3	85	9.5	5.00	0.147	0.150	PASS
4	85	9.1	5.00	0.327	0.330	PASS
5	85	9.1	5.00	0.312	0.316	PASS
6	85	9.6	5.00	0.296	0.306	PASS
7	85	9.7	5.00	0.314	0.315	PASS
8	85	9.1	5.00	0.325	0.335	PASS
9	85	9.2	5.00	0.246	0.253	PASS
10	85	9.4	5.00	0.383	0.385	PASS
11	85	9.5	5.00	0.283	0.290	PASS
12	85	10.0	5.00	0.444	0.446	PASS
13	85	9.9	5.00	0.327	0.327	PASS
14	85	9.0	5.00	0.740	0.793	PASS
15	85	8.2	5.00	0.412	0.437	PASS
16	85	9.0	5.00	0.356	0.369	PASS
17	85	8.9	5.00	0.338	0.351	PASS
18	85	8.8	5.00	0.480	0.489	PASS
19	85	9.1	5.00	0.374	0.384	PASS
20	85	8.4	5.00	0.515	0.552	PASS

Overall Result: PASS

Signature:

Engineering Technician

Date: 7/12/2006

Task Number: TN-14513

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Shanghai Dasheng Health Products Manufacture

Item Tested: DTC3X

Comments:

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

☒ Yes ☐ No

Signature:



Engineering Technician

Date: 6/29/2006

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



Task Number: TN-14513

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Shanghai Dasheng Health Products Manufacture

Item Tested: DTC3X

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	9.4	PASS
2	35	9.1	PASS
3	35	9.1	PASS

Overall Result: PASS

Signature:

A handwritten signature in black ink, appearing to read "Jeremy B. Bannister". The signature is written in a cursive, flowing style.

Engineering Technician

Date: 6/29/2006

Task Number: TN-14513

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Shanghai Dasheng Health Products Manufacture

Item Tested: DTC3X

Comments:

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

☒ Yes ☐ No

Signature:



Engineering Technician

Date: 6/29/2006

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



Task Number: TN-14513

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Shanghai Dasheng Health Products Manufacture

Item Tested: DTC3X

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Exhalation	Exhalation	
1	25	7.9	PASS
2	25	7.9	PASS
3	25	7.9	PASS

Overall Result: PASS

Signature:

A handwritten signature in black ink, appearing to read "Jeremy B. Bannister".

Engineering Technician

Date: 6/29/2006

REGISTRO SANITARIO

VISTOS:

El expediente N° **422363** presentado por el Regente Farmaceutico(a)
FABIOLA XIMENA MONTESINOS RODRIGUEZ con Matrícula N° **M-1088** en representación de la firma
EQUIPOS Y HERRAMIENTAS HERRACRUZ S.A. por el que solicita la **INSCRIPCION** del producto
DISPOSITIVO MED - DISPOSABLE DUST FACEMASK N95 MODEL DTC-1X- para su **IMPORTACION**
y comercialización en el país, elaborado por: **SHANGHAI DASHENG HEALTH PRODUCTS MANUFACTURE CO. LTD.**
de **CHINA** para bajo licencia de

VICSA SAFETY LTDA.

Con aval de la Comisión Farmacológica Nacional: /

Certificado de Control de Calidad: / - NO REQUIERE

CONSIDERANDO:

Qué se han cumplido con todos los requisitos, por tanto:

SE RESUELVE:

Autorizar la **INSCRIPCION** en el Registro Sanitario Nacional del producto
DISPOSITIVO MED - DISPOSABLE DUST FACEMASK N95 MODEL DTC-1X- de laboratorios
SHANGHAI DASHENG HEALTH PRODUCTS MANUFACTURE CO. LTD. procedente de **CHINA**
para bajo licencia de
VICSA SAFETY LTDA. bajo el N° **DI-74397/2020.**
que responde a las siguientes especificaciones:

Formula aprobada:

/

CAJA BLANCA DE CARTON QUE CONTIENE 20 UNIDADES DEL PRODUCTO

Presentación:

Condición de venta: **VENTA LIBRE**

Periodo de validez: **36 MESES**

Orden de pago N° **5129310/2020** del **14** de **Julio** de **2020**

EL presente Registro Sanitario tiene validez de cinco años a partir de la fecha:

La Paz, **28** de **Julio** de **2020**


Dra. Mayra P. Cipriano Quispe
JEFE DPTO. DE AUTORIZACIÓN
DE COMERCIALIZACIÓN S.J.
AGENCIA ESTATAL DE MEDICAMENTOS
Y TECNOLOGÍAS EN SALUD
AGEMED

Regístrese, comuníquese y archive




Dra. Eliana Coballero Vedia
DIRECTORA GENERAL EJECUTIVA S.J.
AGENCIA ESTATAL DE MEDICAMENTOS
Y TECNOLOGÍAS EN SALUD
AGEMED