大胜口罩

以下 2-1——2-5 是同一家公司的五款不同类型的产品，都有 CE、FDA 等资质认证。

目前日产能 5-8 万个，月保守产能 200 万个。

2-1 DTC3B

CE 认证：


INSPEC

EU TYPE-EXAMINATION CERTIFICATE

This is to certify that the Personal Protective Equipment type, in respect of the product detailed on this certificate, has been evaluated and deemed to be in compliance with Regulation (EU) 2016/425 Module B, and the applicable Essential Health & Safety Requirements.

Manufacturer:

Compliance with the applicable Essential Health & Safety Requirements has been demonstrated as above, including examination in accordance with the harmonised standard below:

EN149:2001 +A1:2009

Product description: Respiratory Protective Devices – Filtering Half Masks;

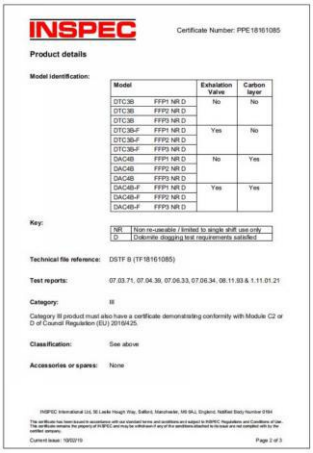
Horizontal Fold Flat Style

DTC3B, DTC3B-F, DAC4B, DAC4B-F

Date of initial certification: 10th February 2019
Date of current issue: 10th February 2019
Date of expiry: 10th February 2024

Technical Director

CE


INSPEC

Certificate Number: PPE18161085

Product details

Model identification:

Model		Exhalation Valve	Carbon layer
DTC3B	FFP1 NR D	No	No
DTC3B	FFP2 NR D		
DTC3B	FFP3 NR D		
DTC3B-F	FFP1 NR D	Yes	No
DTC3B-F	FFP2 NR D		
DTC3B-F	FFP3 NR D		
DAC4B	FFP1 NR D	No	Yes
DAC4B	FFP2 NR D		
DAC4B	FFP3 NR D		
DAC4B-F	FFP1 NR D	Yes	Yes
DAC4B-F	FFP2 NR D		
DAC4B-F	FFP3 NR D		

Key:

NR	Non re-useable / limited to single shift use only
D	Dolomite clogging test requirements satisfied

Technical file reference: DSTF B (TF18161085)

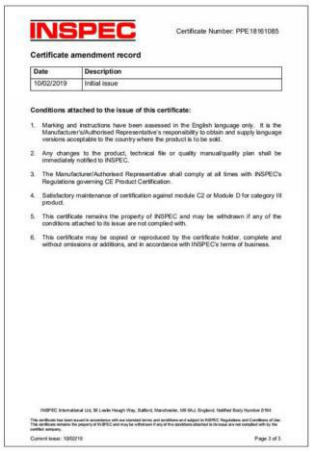
Test reports: 07.03.71, 07.04.39, 07.06.33, 07.06.34, 08.11.93 & 1.11.01.21

Category: III

Category III product must also have a certificate demonstrating conformity with Module C2 or D of Council Regulation (EU) 2016/425.

Classification: See above

Accessories or spares: None


INSPEC

Certificate Number: PPE18161085

Certificate amendment record

Date	Description
10/02/2019	Initial issue

Conditions attached to the issue of this certificate:

1. Marking and instructions have been assessed in the English language only. It is the Manufacturer's/Authorised Representative's responsibility to obtain and supply language versions acceptable to the country where the product is to be sold.
2. Any changes to the product, technical file or quality manual/quality plan shall be immediately notified to INSPEC.
3. The Manufacturer/Authorised Representative shall comply at all times with INSPEC's Regulations governing CE Product Certification.
4. Satisfactory maintenance of certification against module C2 or Module D for category III product.
5. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.
6. This certificate may be copied or reproduced by the certificate holder, complete and without omissions or additions, and in accordance with INSPEC's terms of business.

2-2 DTC3W

INSPEC

Certificate Number: PPE18161037

Certificate amendment record

Date	Description
23 October 2018	Add DAC4MxF FFP2 NR due to typo
13 September 2018	Initial issue

Conditions attached to the issue of this certificate:

1. Marking and instructions have been assessed in the English language only. It is the Manufacturer's/Authorised Representative's responsibility to obtain and supply language versions acceptable to the country where the product is to be sold.
2. Any changes to the product, technical file or quality manual/quality plan shall be immediately notified to INSPEC.
3. The Manufacturer/Authorised Representative shall comply at all times with INSPEC's Regulations governing CE Product Certification.
4. Satisfactory maintenance of certification against module C2 or Module D for category III product.
5. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.
6. This certificate may be copied or reproduced by the certificate holder, complete and without omissions or additions, and in accordance with INSPEC's terms of business.

INSPEC International Ltd, 56 Leslie Hough Way, Salford, Manchester, M6 6AJ, England. Notified Body Number 0164

This certificate has been issued in accordance with our standard terms and conditions and subject to INSPEC Regulations and Conditions of Use. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with by the certified company.

Current issue: 23/10/18

Page 4 of 4

2-3 DTC3X

CE 认证：

FDA 认证：

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2009

Ms. Maggie Zhong
Shanghai Dasheng Health Products
Number 228 Shihui Road Zhongshan Street
Songjiang District
Shanghai, CHINA

Re: K090131
Trade/Device Name: DS N95 Surgical Masks and Flat Surgical Masks for Single Use
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH, FXX
Dated: April 8, 2009
Received: April 13, 2009

Dear Ms. Zhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

Page 2- Ms. Zhong

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K090131
APPLICANT: Shanghai Dasheng Health Products Manufacture Co. Ltd
DEVICE NAME:
DS N95 Surgical Masks and Flat Surgical Masks for single use

DS Surgical Ear-Loop Masks - Blue(FDB), Pink(FDP), Green(FDG), Yellow(FDY), White(FDW), Orange(FDO).
DS Surgical Tie-On Masks - Blue(FTB), Pink(FTP), Green(FTG), Yellow(FTY), White(FTW), orange(FTO).

INDICATION FOR USE:
The DS N95 Surgical Masks DTC3M-1/DTC3B, and flat surgical masks are intended for single use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

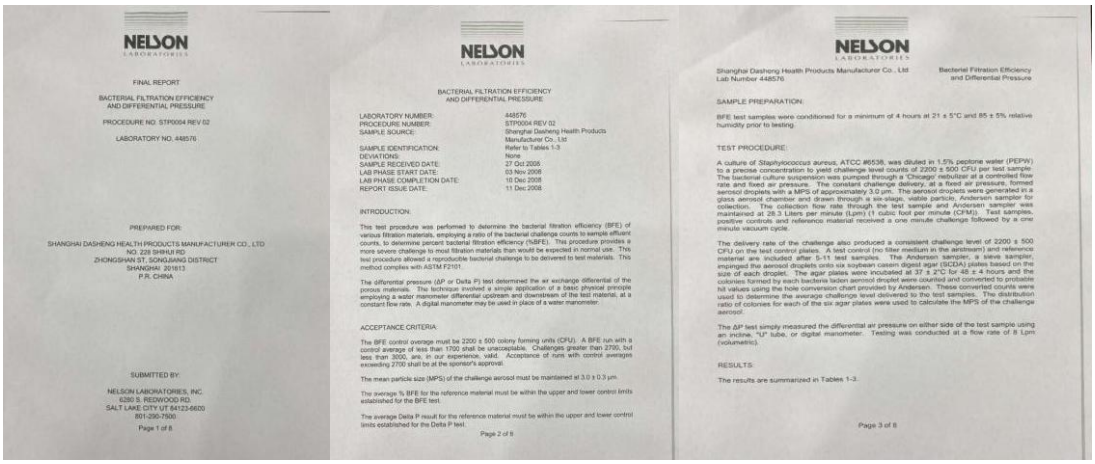
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090131

Page 1 of ____

NELSON 认证：



NELSON LABORATORIES

FINAL REPORT

BACTERIAL FILTRATION EFFICIENCY
AND DIFFERENTIAL PRESSURE

PROCEDURE NO. STP0004 REV 02

LABORATORY NO. 448576

PREPARED FOR:

SHANGHAI DASHENG HEALTH PRODUCTS MANUFACTURER CO., LTD
NO. 228 SHIHUI RD
ZHONGSHAN ST, SONGJIANG DISTRICT
SHANGHAI 201613
P.R. CHINA

SUBMITTED BY:

NELSON LABORATORIES, INC.
6280 S. REDWOOD RD.
SALT LAKE CITY UT 84123-6600
801-290-7500

Page 1 of 8

NELSON LABORATORIES

BACTERIAL FILTRATION EFFICIENCY
AND DIFFERENTIAL PRESSURE

LABORATORY NUMBER:	448576
PROCEDURE NUMBER:	STP0004 REV 02
SAMPLE SOURCE:	Shanghai Dasheng Health Products Manufacturer Co., Ltd
SAMPLE IDENTIFICATION:	Refer to Tables 1-3
DEVIATIONS:	None
SAMPLE RECEIVED DATE:	27 Oct 2008
LAB PHASE START DATE:	03 Nov 2008
LAB PHASE COMPLETION DATE:	10 Dec 2008
REPORT ISSUE DATE:	11 Dec 2008

INTRODUCTION:

This test procedure was performed to determine the bacterial filtration efficiency (BFE) of various filtration materials, employing a ratio of the bacterial challenge counts to sample effluent counts, to determine percent bacterial filtration efficiency (%BFE). This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This test procedure allowed a reproducible bacterial challenge to be delivered to test materials. This method complies with ASTM F2101.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate. A digital manometer may be used in place of a water manometer.

ACCEPTANCE CRITERIA:

The BFE control average must be 2200 ± 500 colony forming units (CFU). A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at the operator's approval.

The mean particle size (MPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 µm.

The average % BFE for the reference material must be within the upper and lower control limits established for the BFE test.

The average Delta P result for the reference material must be within the upper and lower control limits established for the Delta P test.

Page 2 of 8

NELSON LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd — Bacterial Filtration Efficiency and Differential Pressure
Lab Number 448576

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity prior to testing.

TEST PROCEDURE:

A culture of *Staphylococcus aureus*, ATCC #6538, was diluted in 1.5% peptone water (PEPW) to a precise concentration to yield challenge level counts of 2200 ± 500 CFU per test sample. The bacterial culture suspension was pumped through a 'Chicago' nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 Liters per minute (Lpm) (1 cubic foot per minute (CFM)). Test samples, positive controls and reference material received a one minute challenge followed by a one minute vacuum cycle.

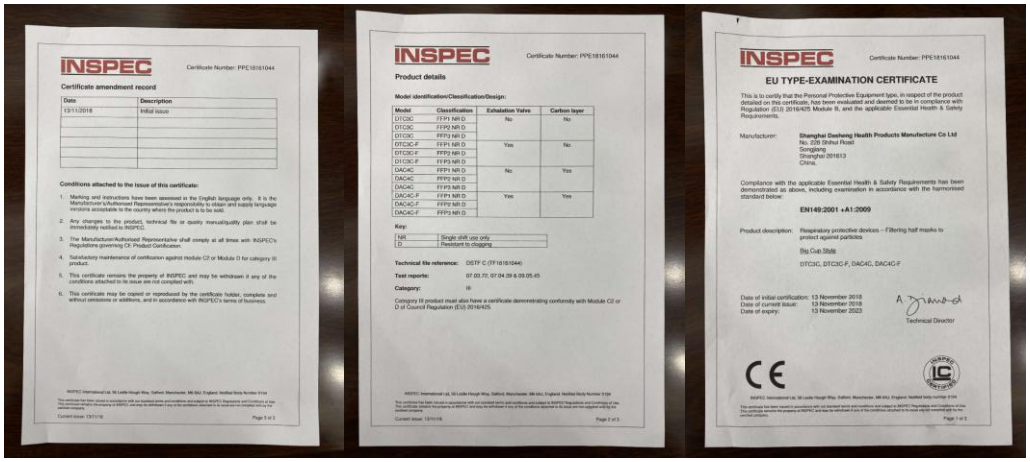
The delivery rate of the challenge also produced a consistent challenge level of 2200 ± 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material are included after 5-11 test samples. The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPS of the challenge aerosol.

The ΔP test simply measured the differential air pressure on either side of the test sample using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 Lpm (volumetric).

RESULTS:

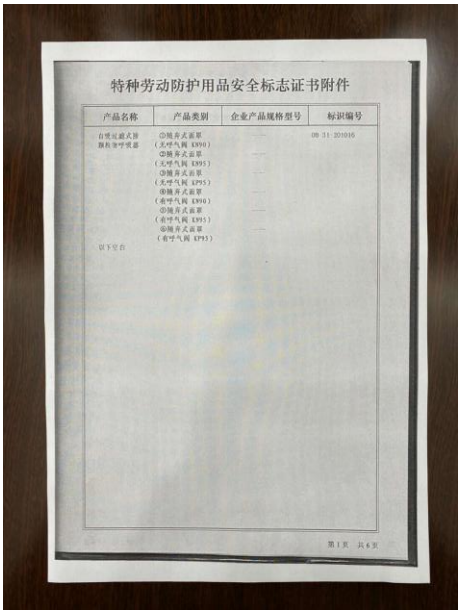
The results are summarized in Tables 1-3.

Page 3 of 8



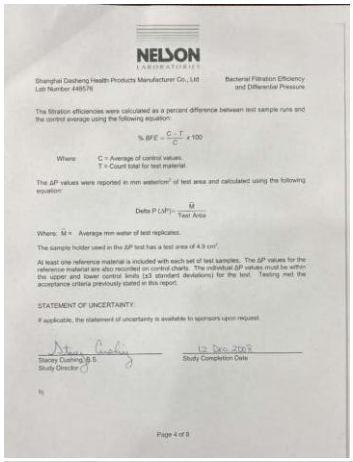
箱规：

包装说明：
P2：52*42*33 毛重 6.1kg 400只
DTC3Z：50*46*28 毛重 5kg 400只
DTC3X：62*29*29 毛重 4.3kg 400只
DTC3W：62*29*34 毛重 5kg 400只
DTC3B：52*42*33 毛重 6.1kg 400只



国标检验报告：

各项资质一览表：



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

The filtration efficiencies were calculated as a percent difference between test sample runs and the control average using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

Where: C = Average of control values.
T = Count total for test material.

The ΔP values were reported in mm water/cm² of test area and calculated using the following equation:

$$\text{Delta P } (\Delta P) = \frac{\bar{M}}{\text{Test Area}}$$

Where: $\bar{M}$ = Average mm water of test replicates.

The sample holder used in the ΔP test has a test area of 4.9 cm².

At least one reference material is included with each set of test samples. The ΔP values for the reference material are also recorded on control charts. The individual ΔP values must be within the upper and lower control limits (±3 standard deviations) for the test. Testing met the acceptance criteria previously stated in this report.

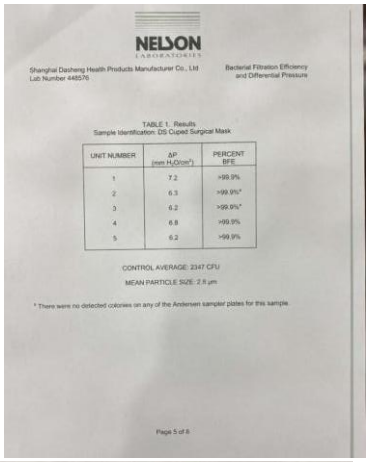
STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

Stacey Cushing, B.S.
Study Director

12 Dec. 2005
Study Completion Date

Page 4 of 8



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 1. Results
Sample Identification: DS Cuped Surgical Mask

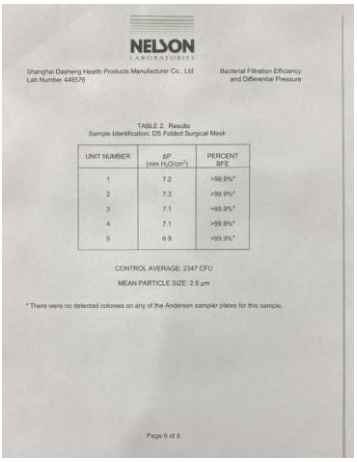
UNIT NUMBER	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	7.2	>99.9%
2	6.3	>99.9%*
3	6.2	>99.9%*
4	6.8	>99.9%
5	6.2	>99.9%

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.5 µm

* There were no detected colonies on any of the Andersen sampler plates for this sample.

Page 5 of 8



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 2. Results
Sample Identification: DS Folded Surgical Mask

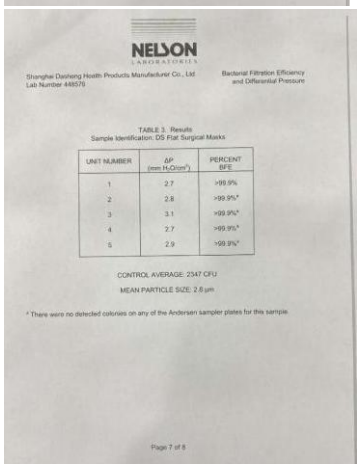
UNIT NUMBER	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	7.2	>99.9%*
2	7.3	>99.9%*
3	7.1	>99.9%*
4	7.1	>99.9%*
5	6.9	>99.9%*

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.5 µm

* There were no detected colonies on any of the Andersen sampler plates for this sample.

Page 6 of 8



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

TABLE 3. Results
Sample Identification: DS Flat Surgical Masks

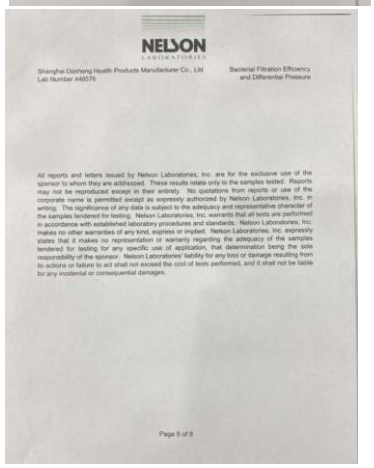
UNIT NUMBER	ΔP (mm H_2O/cm^2)	PERCENT BFE
1	2.7	>99.9%
2	2.8	>99.9%*
3	3.1	>99.9%*
4	2.7	>99.9%*
5	2.9	>99.9%*

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.6 µm

* There were no detected colonies on any of the Andersen sampler plates for this sample.

Page 7 of 8



NELSON
LABORATORIES

Shanghai Dasheng Health Products Manufacturer Co., Ltd
Lab Number 448576

Bacterial Filtration Efficiency
and Differential Pressure

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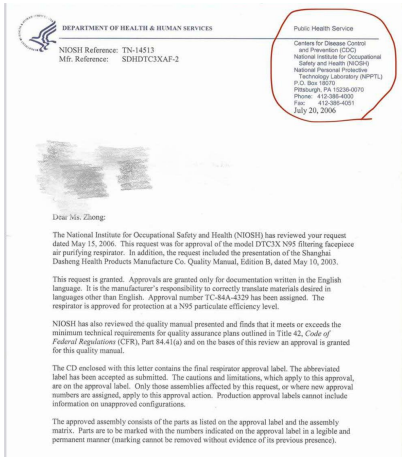
NIOSH 认证：



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NIOSH Reference: TN-14513
Mfr. Reference: SDHDTC3XAF-2

[redacted]

Dear Ms. Zhong:

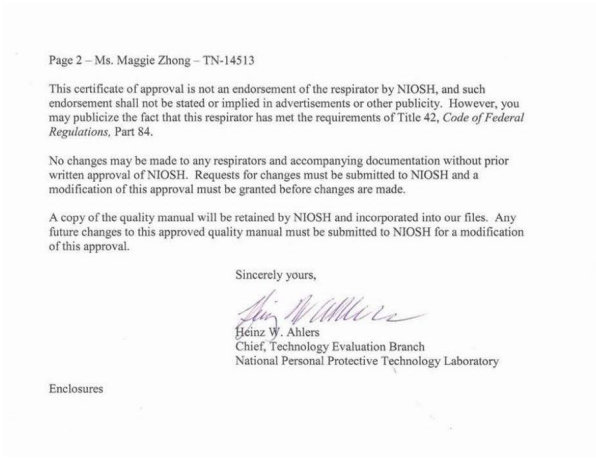
The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 15, 2006. This request was for approval of the model DTC3X N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Dasheng Health Products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



Page 2 – Ms. Maggie Zhong – TN-14513

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.

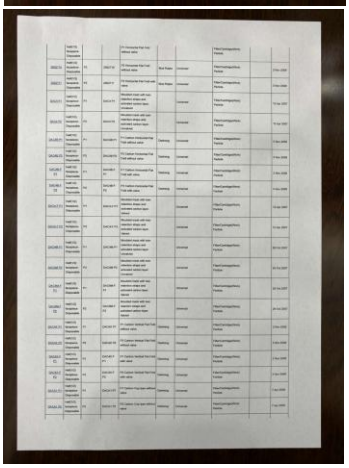
A copy of the quality manual will be retained by NIOSH and incorporated into our files. Any future changes to this approved quality manual must be submitted to NIOSH for a modification of this approval.

Sincerely yours,

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

Enclosures

澳洲资质：




SAI GLOBAL

Shanghai Da Sheng Health Products Co Ltd