Certificate of Registration

nqa.

This is to certify that the Quality Management System of

Shanghai Dasheng Health Products Manufacture Co., Ltd.

Unified Social Credit Code： 9131011760737834l5
Operation Address : No.228 Shihui Road, Songjiang District, Shanghai, China
Registered Address : No.228 Shihui Road, Songjiang District, Shanghai, China

applicable to

Production and sales of disposable non-sterilizing nonwoven fabric mask

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **44710**

Date: 23 April 2018
Valid Until: 23 April 2021
EAC Code: 04

UKAS MANAGEMENT SYSTEMS
015

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

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

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

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).

CERTIFICATION SCHEDULE

Single Shift Use Particle Filtering Half Mask

Model	Class	Valve	Carbon
DTC3X	FFP1 NR, FFP2 NR, FFP3 NR	No	No
DTC3X-F	FFP1 NR, FFP2 NR, FFP3 NR	Yes	No
DAC4X	FFP1 NR, FFP2 NR, FFP3 NR	No	Yes
DAC4X-F	FFP1 NR, FFP2 NR, FFP3 NR	Yes	Yes

CERTIFICATION INDEX

Item	Status	Issued	Amendment
Pages 1 and 2	Withdrawn		Transfer to new certificate
Schedule ONE	Withdrawn		
Page 1 of 4	Withdrawn	061020	New company address and EU representative
Page 2 of 4	Withdrawn	061020	
Page 3 of 4	Withdrawn	061020	Technical Ref. TF/1498
Page 4 of 4	Withdrawn	061020	Model references and designations
Pages 1 to 4	Withdrawn	070426	Addition of DAC4 models. Addition of 120mg loading
Pages 1 to 4	Valid	100410	To upgrade the existing certified models to EN149:2001 +A1:2009

Terms and Conditions

Reference Documents: -

i)	Test Reports	-	INSPEC, 04.10.16, 05.06.13, 07.04.08 & 07.04.39
ii)	Technical File	-	Ref: TF/1498 and TF/1587
iii)	Test and Inspection Plan	-	Dasheng Finished Products Test Plan dated 20th March 2006 & 1st Feb 2010.

Conditions attached to the issue of this certificate:

i) Marking and instructions have been assessed in the English language only. It is the Manufacturers/Authorised Representatives responsibility to obtain and supply language versions acceptable to the country where the product is to be sold.

ii) Any changes to the product, technical file or quality manual/quality plan shall be immediately notified to INSPEC.

iii) The Manufacturer/Authorised Representative shall comply at all times with INSPEC's Regulations governing CE Product Certification.

iv) Satisfactory maintenance of independent certification against Article 11.B of the P.P.E. Directive.

v) This Certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.

INSPEC

CE

EC TYPE-EXAMINATION CERTIFICATE: 1587

Product description: - Single Shift Use Filtering Half Masks

Product identification: - See Schedule

Manufacturer: -

Shanghai Dasheng Health
Products Manufacture Co Ltd
228 Shihui Road, Zhongshan District,
Songjiang, Shanghai 201613, China

When assessed and examined against harmonised standard EN149:2001+A1:2009 are found to be in conformity with Council Directive 89/686/EEC and associated amendments, relating to personal protective equipment.

And

Are manufactured under a Quality Control System, which has been satisfactorily assessed as meeting the requirements of Article 11 Section B of the same Directive.

Authorised EU Representative: -

Algate Business Solutions Ltd.
23 Balfern Grove
Chiswick, London W4 2JX

Signed: **Date: 20th October 2006**

K J Warren, Manager, Certification Services

For and on behalf of INSPEC International Ltd.
(Notified Body No: 0194)

certificate invalid
if not embossed

For terms and conditions of issue, see page 2

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

DTC3M-1, DTC3B Surgical N95 Respirator

DS Surgical **Ear-Loop** Masks – Blue(FE3B), Pink(FE3P), Green(FE3G), Yellow(FE3Y), White(FE3W), Orange(FE3O)

DS Surgical Fog Free **Ear-Loop** Masks- Blue(FE3B-O), Pink(FE3P-O), Green(FE3G-O), White(FE3W-O), Orange(FE3O-O), Yellow(FE3Y-O),

DS Surgical **Ear-Loop** Masks **with** splash visor – Blue(FE3B-A), Pink(FE3P-A), Orange(FE3O-A), white(FE3W-A), Yellow(FE3Y-A), Green(FE3G-A)

DS Surgical **Tie-On** Masks – Blue(FT3B), Pink(FT3P), Green(FT3G), Yellow(FT3Y), White(FT3W), orange(FT3O)

DS Surgical Fog Free **Tie-On** Masks - Blue(FT3P-O), Pink(FT3P-O), Green(FT3G-O), Yellow(FT3Y-O), White(FT3W-O), Orange(FT3O-O)

DS Surgical **Tie-On** Masks **with** splash visor - Blue(FT3B-A), White(FT3W-A), Orange(FT3O-A), Yellow(FT3Y-A), Pink(FT3P-A), Green(FT3G-A)

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)

Concurrrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090131

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 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.

INSPEC

CE

EC TYPE-EXAMINATION CERTIFICATE: 1587

Product description: - Filtering Half masks to Protect against Particles – Single Use.

Product identification: - DTC3X, DTC3X-F, DAC4X, DAC4X-F
See Schedule

Manufacturer: - Shanghai Dasheng Health Products Manufacture Co Ltd
228 Shihui Road, Zhongshan District,
Songjiang, Shanghai, 201613 PRC

When assessed and examined against harmonised standard EN149:2001 and 120mg loading, are found to be in conformity with Council Directive 89/686/EEC and associated amendments, relating to personal protective equipment.

And

Are manufactured under a Quality Control System, which has been satisfactorily assessed as meeting the requirements of Article 11 Section B of the same Directive.

Authorised EU Representative: - **Algate Business Solutions Ltd.**
23 Balfern Grove
Chiswick, London W4 2JX

Signed **Date: 20th October 2006**

K J Warren, Manager, Certification Services

For and on behalf of INSPEC International Ltd.
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