PPE

Personal Protective Equipment

Dasheng

Dasheng

Dasheng was established in 1997, and now possesses of 20000M2 modern factory plant. Dasheng holds 13 senior engineers and more than 300 sets of mask making machines. Recently Dasheng has developed new auto-matic production lines with 60 machines, and applied for copyrights. All these make the annual capacity of dust mask/ respirators as 200 million pieces, and brought Dasheng to be the leader of mask industry. Products are classified as over 100 items, and exported to USA, Canada, South Africa, Australia, Europe, Japan, Korea, Malaysia, Singapore, Russia, Hongkong, Taiwan, etc over 60 countries and areas.

1997-2017

Dasheng Brand is registered by Chinese People's Republic Brand Bureau and also registered in oversea countries, such as USA, Canada, South Africa, Australia, Europe, Japan, etc. Based on the national standard LD29-2006, GB/T2626-2006, GB2828-87, GB2829-87 and combined with the different standards in different countries, Dasheng masks are developed and manufactured to fit different people with various faces from all over the world.

Dasheng is certified with ISO9001:2008 International Quality Management System. The products meet Europe Standard EN149:2001+A1:2009 with FFP1 NR/ FFP2 NR/ FFP3 NR grades, Australia standard AS/NZS1716:2003 and American standard NIOSH N95/ N99, FDA(510K), Japanese standard DS-2. Dasheng's twin-valve mask, net surface mask, camo-war mask, anti-fire mask, multiple folded mask, anti-virus mask, as well as Hi-tech of foldable structure, whose advantage to enlarge inner space and no move when speaking, have registered for national copyright.

Dasheng has five production lines of masks. Workers work in two shifts around the clock.

Factory manager Zhang Weizhen

FDA: SHANGHAI DASHENG HEALTH PRODUCTS MANUFACTURE CO.
No.228 Shihui Road,
Songjiang, Shanghai
SHANGHAI Shanghai, CN 201613
Registration Number: 3006534188
FEI Number*: 3006534188

Nothing is more important than breathing Dasheng

Device Classification Name	Respirator, Surgical
510(K) Number	K090131
Device Name	DS N95 SURGICAL MASKS AND FLAT S.
Proprietary Name:	DUKAL CORPORATION
Classification Name:	RESPIRATOR, SURGICAL
Product Code:	MSH
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	SHANGHAI DASHENG HEALTH PROD. MANUFACTURE CO. LTD
Registered Establishment Number:	3006534188
Premarket Submission Number:	K070692
Owner/ Operator	SHANGHAI DASHENG HEALTH PROD. MANUFACTURE CO. LTD
Owner/ Operator Number:	9099961

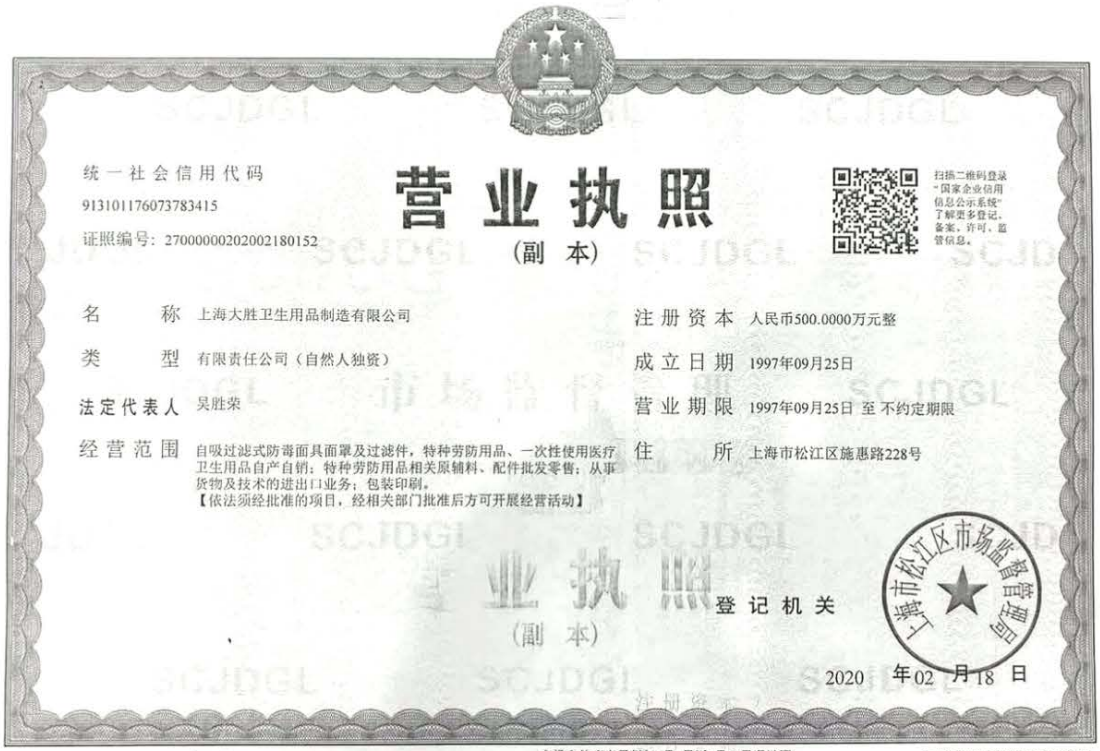
Dasheng masks all use non-toxic, tasteless, non-allergic, non-stimulating, without any toxic and hazardous substances and glass fiber polypropylene as the main raw materials, humanized design, selection of high standard, high quality manufacturing, factory quality, multi-standard products, multi-country international certification, multi-level face of the global market. Dasheng masks with soft plump, high efficiency filter, anti-toxicity, anti-virus, odor, breathable comfort and health, convenience, safety and aesthetic characteristics.

International Organization for Standardization ISO 13485

INTERNATIONAL CERTIFICATIONS ISO 9001


Dasheng


7



统一社会信用代码

91310117607378341 5

证照编号：27000000202002180152

营业执照

（副本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　上海大胜卫生用品制造有限公司

类　　型　有限责任公司（自然人独资）

法定代表人　吴胜荣

经营范围　自吸过滤式防毒面具面罩及过滤件，特种劳防用品、一次性使用医疗卫生用品自产自销；特种劳防用品相关原辅料、配件批发零售；从事货物及技术的进出口业务；包装印刷。【依法须经批准的项目，经相关部门批准后方可开展经营活动】

注册资本　人民币500.0000万元整

成立日期　1997年09月25日

营业期限　1997年09月25日 至 不约定期限

住　　所　上海市松江区施惠路228号

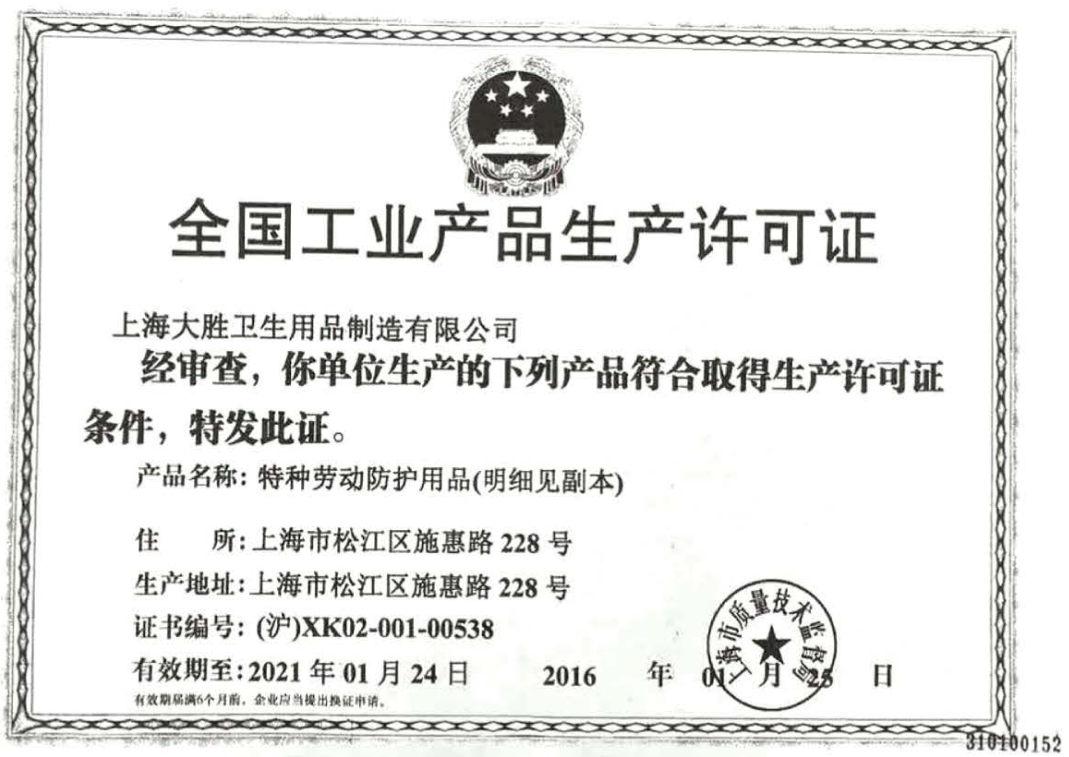
登记机关　上海市松江区市场监督管理局

2020 年02 月18 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制



全国工业产品生产许可证

上海大胜卫生用品制造有限公司

经审查，你单位生产的下列产品符合取得生产许可证条件，特发此证。

产品名称：特种劳动防护用品(明细见副本)

住　　所：上海市松江区施惠路 228 号

生产地址：上海市松江区施惠路 228 号

证书编号：(沪)XK02-001-00538

有效期至：2021 年 01 月 24 日　　2016 年 01 月 25 日

有效期届满6个月前，企业应当提出换证申请。

上海市质量技术监督局

310100152

特种劳动防护用品安全标志证书

上海大胜卫生用品制造有限公司

生产的特种劳动防护用品，经审查，符合特种劳动防护用品安全标志规定的要求，特发此证。

具体产品名称、产品类别、企业产品规格型号及标识编号见特种劳动防护用品安全标志证书附件。

证书编号：LA 2008 0824

有效期至 2020 年 9 月 25 日

年 检 情 况

2017 年	2018 年	2019 年

特种劳动防护用品安全标志管理中心

二〇一六年九月二十六日


Dasheng

PPE

Personal Protective Equipment

Dasheng

The N95 respiratory mask follows the National Institute for Occupational Safety and Health (NIOSH), under authorization of the Occupational Safety and Health Act of 1970.

N95 respiratory mask has a filtration efficiency of ≥95% and is suitable for filtering oily and non-oily particulate matter. This face mask can effectively filter and purify absorb harmful aerosols, including dust, fume, mist, poisonous gases, and help reduce certain inhalable microbial particles (such as mold, anthracnose, tuberculosis, etc.).

International Organization for Standardization ISO 13485

INTERNATIONAL CERTIFICATIONS ISO 9001

Dasheng

Nothing is more important than breathing

Dasheng

N95 respirators

DTC3X N95 respirator, NIOSH TC-84A-4329

NIOSH certified and FDA 510(k) cleared

Tight-fitting, anti-blood permeability, surface moisture resistance

Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).

CDC Centers for Disease Control and Prevention

86-21-5778-3126

MADE IN CHINA

National Institute for Occupational Safety and Health NIOSH

FDA APPROVED

Nothing is more important than breathing

Dasheng

Surgical N95 respirators

Model:DTC3M-1 84A-4331 and Model: DTC3B 84A-4336

NIOSH certified and FDA 510(k) cleared

Tight-fitting, anti-blood permeability, surface moisture resistance

Single-use, disposable respiratory protective devices used and worn by health care personnel during procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate material.

SMMMS multilayer structure, the inner and outer layers are spunbond non-woven fabrics, and the middle layer is meltblown fabrics.

DTC3M-1 (No Valve): 20 pcs / box, 20 boxs / carton = 400 pcs (70cm x 30cm x 35cm, about 6KG).

CDC Centers for Disease Control and Prevention

86-21-5778-3126
86-21-5778-3126

MADE IN CHINA

National Institute for Occupational Safety and Health NIOSH

FDA APPROVED

Nothing is more important than breathing Dasheng

Dasheng masks are safe and reliable!

Breathing protection, breathing apparatus, respirators

Packing specification: 20PCS / box; 20box / carton

CDC Centers for Disease Control and Prevention

86-21-5778-3126

This mask is a regular medical grade N95 and is recommended for use by frontline healthcare workers.

MADE IN CHINA

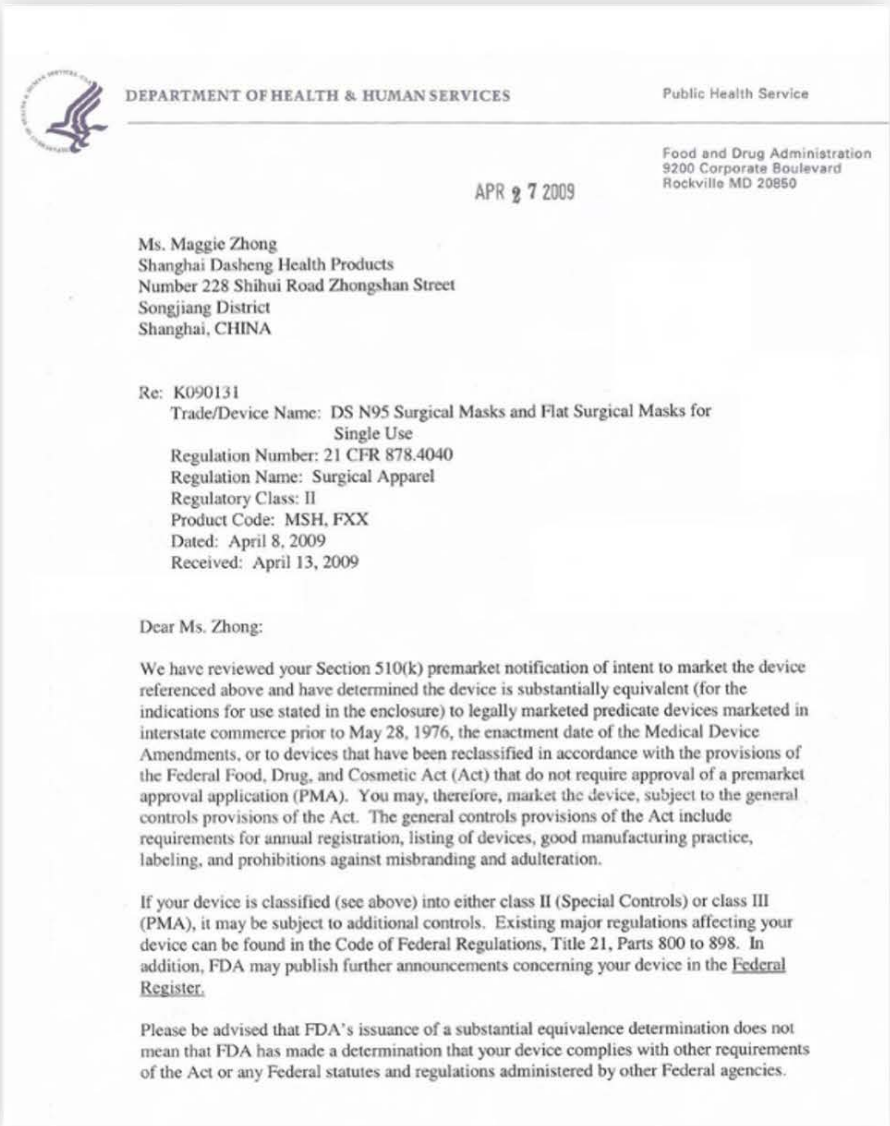
NIOSH National Institute for Occupational Safety and Health

FDA APPROVED


Dasheng


N95
N95
N95


上海大胜
Shanghai Dasheng



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.

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

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).

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


Dasheng


N95
N95
N95


上海大胜
Shanghai Dasheng

Nothing is more important than breathing

Dasheng

Type	Surgical Mask	N95 Respirator	Surgical N95s Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84	Surgical N95s respirators are both certified by NIOSH as an N95 respirator and also cleared by the FDA as a surgical mask.
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).	A surgical N95s (also referred as a medical respirator) is recommended only for use by healthcare personnel (HCP) who need protection from both airborne and fluid hazards (e.g., splashes, sprays).
Face Seal Fit	Loose-fitting	Tight-fitting	
Fit Testing Requirement	No	Yes	
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)	
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles	
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales	
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosolgenerating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.	

US - NIOSH 42 CFR				
Level	/	N95	N99	N100
Particulate Filtration Efficiency	/	PFE ≥ 95%	PFE ≥ 99%	PFE ≥ 99.97%
Differential Pressure	/	≤ 35 mm H_2O / cm^2	≤ 35 mm H_2O / cm^2	≤ 35 mm H_2O / cm^2

International Organization for Standardization ISO 13485

INTERNATIONAL CERTIFICATIONS ISO 9001

What about valves?

Respirators with exhalation valves should not be used in situations where a sterile field is required (e.g., during an invasive procedure in an operating or procedure room) because the exhalation valve allows unfiltered exhaled air to escape into the sterile field.
The use of an exhalation valve reduces exhalation resistance, which makes it easier to breathe (exhale). Some users feel that a respirator with an exhalation valve keeps the face cooler and reduces moisture build up inside the facepiece.

How long can this N95 be used for:

The current NIOSH service-time-limit recommendations for non-powered particulate filter respirators are that filter elements should be replaced at the following frequencies: The service life of all filters on NIOSH-approved respirators is limited by considerations of hygiene, damage, and breathing resistance. All filters should be replaced whenever they are damaged, soiled, or causing noticeably increased breathing resistance.

N-series filters generally should be used and reused subject only to considerations of hygiene, damage, and increased breathing resistance. However, for dirty workplaces that could result in high filter loading (i.e., 200 mg), service time for N-series filters should only be extended beyond eight hours of use (continuous or intermittent) by performing an evaluation in specific workplace settings that demonstrates: (a) that extended use will not degrade the filter efficiency below the efficiency level specified in 42 CFR 84, or (b) that the total mass loading of the filter(s) is less than 200 mg. These determinations would need to be repeated whenever conditions change or modifications are made to processes that could change the type of particulate generated in the user's facility.

NOTICE:

1. Wash your hands before wearing the N95 mask, or do not touch the inside of the mask while wearing it to reduce the risk of contamination.

2. Distinguish the inside and outside of the mask, up and down.

3. Do not squeeze the mask with your hands. N95 masks can only isolate the virus on the surface of the mask. If you squeeze the mask with your hands, the virus is drenched in the mask with drops, which can easily cause a virus infection.

4. Make sure the mask fits well on the face. A simple test is: exhale so hard after the mask that no air escapes from the edge of the mask.

5. The mask should be close to the user's face and the user should shave to ensure that the mask can be closed to the face. The beard and everything between the mask seal and the face can cause the mask to leak.

6. After adjusting the position of the mask to the shape of your face, press the nose clip with the index finger of both hands along the top of the mask to make it close to your face.

CHANGE THE MASK IN TIME WHEN:

1. When the respiratory impedance clearly increases;

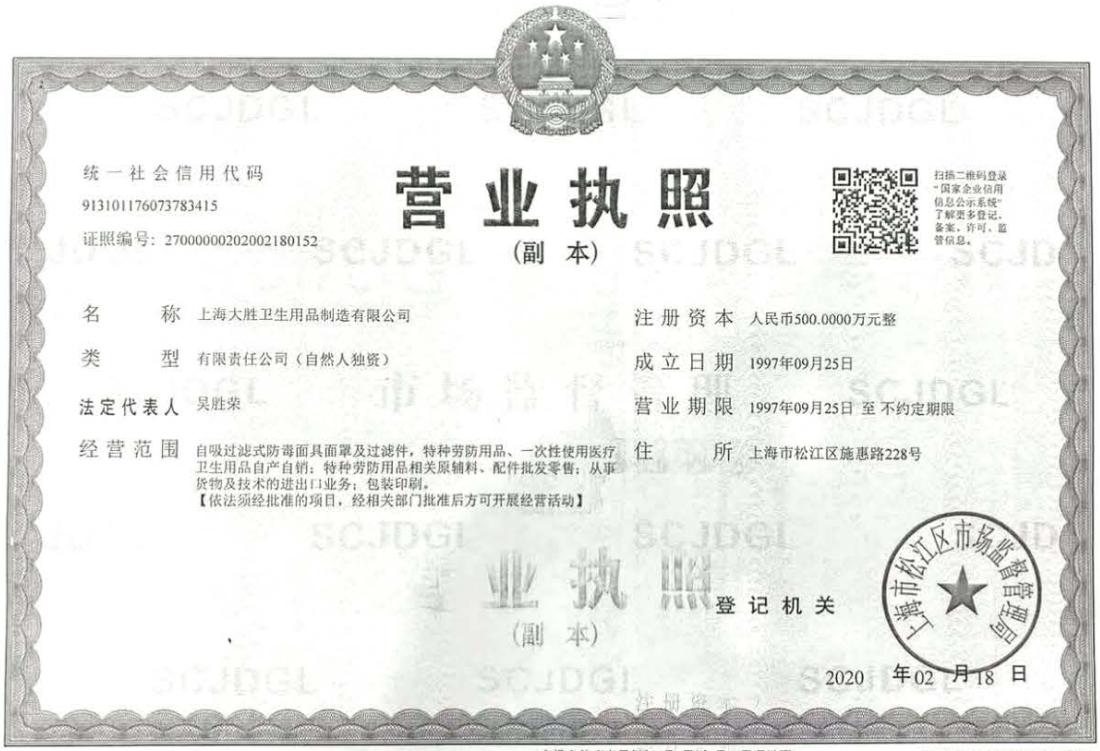
2. If the mask is damaged or damaged;

3. The mask does not come close to the face;

4. Mask contaminated (eg With foreign matter such as blood or drops);

5. The mask is contaminated (in contact with the patient);

6. Use of mask is longer than recommended.



统一社会信用代码

91310117607378341 5

证照编号：27000000202002180152

营业执照

（副本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　上海大胜卫生用品制造有限公司

类　　型　有限责任公司（自然人独资）

法定代表人　吴胜荣

经营范围　自吸过滤式防毒面具面罩及过滤件，特种劳防用品、一次性使用医疗卫生用品自产自销；特种劳防用品相关原辅料、配件批发零售；从事货物及技术的进出口业务；包装印刷。【依法须经批准的项目，经相关部门批准后方可开展经营活动】

注册资本　人民币500.0000万元整

成立日期　1997年09月25日

营业期限　1997年09月25日 至 不约定期限

住　　所　上海市松江区施惠路228号

登记机关　上海市松江区市场监督管理局

2020 年02 月18 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

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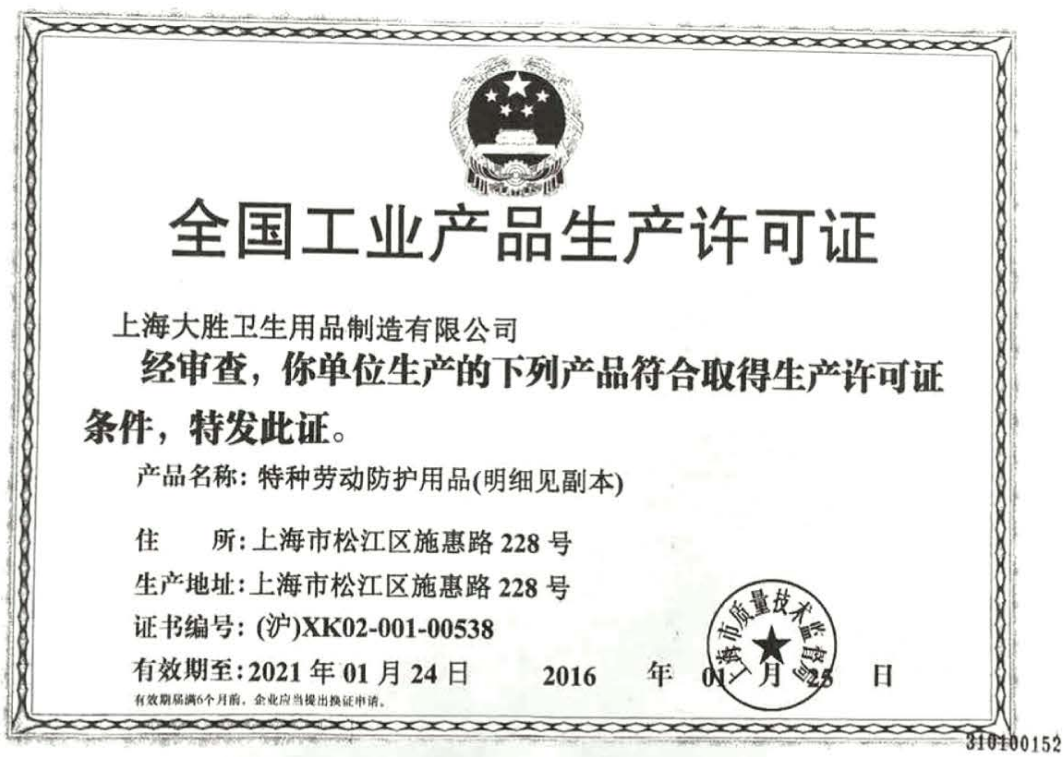
国家市场监督管理总局监制



全国工业产品生产许可证

上海大胜卫生用品制造有限公司

经审查，你单位生产的下列产品符合取得生产许可证条件，特发此证。

产品名称：特种劳动防护用品(明细见副本)

住　　所：上海市松江区施惠路 228 号

生产地址：上海市松江区施惠路 228 号

证书编号：(沪)XK02-001-00538

有效期至：2021 年 01 月 24 日　　2016 年 01 月 25 日

有效期届满6个月前，企业应当提出换证申请。

310100152

特种劳动防护用品安全标志证书

上海大胜卫生用品制造有限公司

生产的特种劳动防护用品，经审查，符合特种劳动防护用品安全标志规定的要求，特发此证。

具体产品名称、产品类别、企业产品规格型号及标识编号见特种劳动防护用品安全标志证书附件。

证书编号：LA 2008 0824

有效期至 2020 年 9 月 25 日

年 检 情 况

2017 年	2018 年	2019 年

二〇一六年九月二十六日

NELSON LABORATORIES

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

Bacterial Filtration Efficiency
and Differential Pressure

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.

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%[a]
3	3.1	>99.9%[a]
4	2.7	>99.9%[a]
5	2.9	>99.9%[a]

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.8 µm

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

NELSON
LABORATORIES

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

Bacterial Filtration Efficiency
and Differential Pressure

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 sponsor'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.

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
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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%[a]
2	7.3	>99.9%[a]
3	7.1	>99.9%[a]
4	7.1	>99.9%[a]
5	6.9	>99.9%[a]

CONTROL AVERAGE: 2347 CFU

MEAN PARTICLE SIZE: 2.8 µm

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

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

大胜口罩国际认证一览表
Dasheng Mask Approved Schedule

Dasheng

认证总数 230 张
Total 230 approvals

CE0194

CE证书共133张（A total of 133 CE approvals）

一、EN149：2001+A1:2009

FFP1 NR (49 types)	DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C(dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3X(dolomite)、DTC3X-F(dolomite)、DTC2X5、DTC2X5-F、DTC3X5、DTC3X5-F、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4X(dolomite)、DAC4X-F(dolomite)、DAC3X5、DAC3X5-F、DAC4X5、DAC4X5-F、DAC4Z(dolomite)、DAC4Z-F(dolomite)
FFP2 NR (41 types)	DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C(dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3X(dolomite)、DTC3X-F(dolomite)、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4X(dolomite)、DAC4X-F(dolomite)、DAC4Z(dolomite)、DAC4Z-F(dolomite)
FFP3 NR (41 types)	DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M、DTC3M-F、DTC3M-1、DTC3M-1F、DTC3C(dolomite)、DTC3C-F(dolomite)、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTC3R、DTC3R-F、DTC3B(dolomite)、DTC3B-F(dolomite)、DTC3XD(dolomite)、DTC3XD-F(dolomite)、DTC3Z(dolomite)、DTC3Z-F(dolomite)、DAC4、DAC4-F、DAC4M、DAC4M-F、DAC4-O、DAC4-OF、DAC4C(dolomite)、DAC4C-F(dolomite)、DAC4M-1、DAC4M-1F、DACA1、DACA1-F、DAC4B(dolomite)、DAC4B-F(dolomite)、DAC4XD(dolomite)、DAC4XD-F(dolomite)、DAC4Z(dolomite)、DAC4Z-F(dolomite)
GOGGLE (2 types)	DS 8810 (Grade F)、DS 8830 (Grade B)

二、AS/NZS1716：2003

澳大利亚证书共52张（A total of 52 AS/NZS approvals）

P1 (26 types)	DAC4、DAC4-F、DTC3B、DTC3B-F、DAC4B、DAC4B-F、DTC3M、DTC3M-F、DAC4M、DAC4M-F、DTC3X、DTC3X-F、DAC4X、DAC4X-F、DTCA1、DTCA1-F、DACA1、DACA1-F、DTCA1N、DTCA1N-F、DACA1N、DACA1N-F、DTC3Z、DTC3Z-F、DAC4Z、DAC4Z-F
P2 (26 types)	DAC4、DAC4-F、DTC3B、DTC3B-F、DAC4B、DAC4B-F、DTC3M、DTC3M-F、DAC4M、DAC4M-F、DTC3X、DTC3X-F、DAC4X、DAC4X-F、DTCA1、DTCA1-F、DACA1、DACA1-F、DTCA1N、DTCA1N-F、DACA1N、DACA1N-F、DTC3Z、DTC3Z-F、DAC4Z、DAC4Z-F

三、NIOSH

NIOSH N95 NIOSH N99

美国N95证书共30张(A total of 30 NIOSH N95 approvals)
美国N99证书共4张（A total of 4 NIOSH N99 approvals）

N95 (30 types)	DTC3W、DTC3W-F、DTC3W-O、DTC3W-OF、DTC3M-1、DTC3C-F、DTC3A、DTC3A-F、DTC3A-2F、DTCA1、DTCA1-F、DTCA1N、DTCA1N-F、DTC3B、DTC3B-F、DTC3X、DTC3X-F、DAC4、DAC4-F、DAC4C、DAC4C-F、DAC4A、DACA1、DACA1-F、DAC4X、DAC4X-F、DAC4B、DAC4B-F、DTC3Z、DTC3Z-F
N99 (4 types)	DTCA1、DTCA1-F、DTCA1N、DTCA1N-F

四、FDA

FDA

FDA证书共3张（A total of 3 FDA approvals）

3-ply facemask in white/ bule/ yellow/ pink/ green，DTC3B N95, DTC3M-1 N95

五、Japan Approved

国(中30)特第TM556号 DR特 DS2

日本DS2证书共8张（A total of 8 DS2 approvals）

European Packaging

Note. US FDA Compliance Labelling/ Packaging

European Packaging

Note. US FDA Compliance Labelling/ Packaging

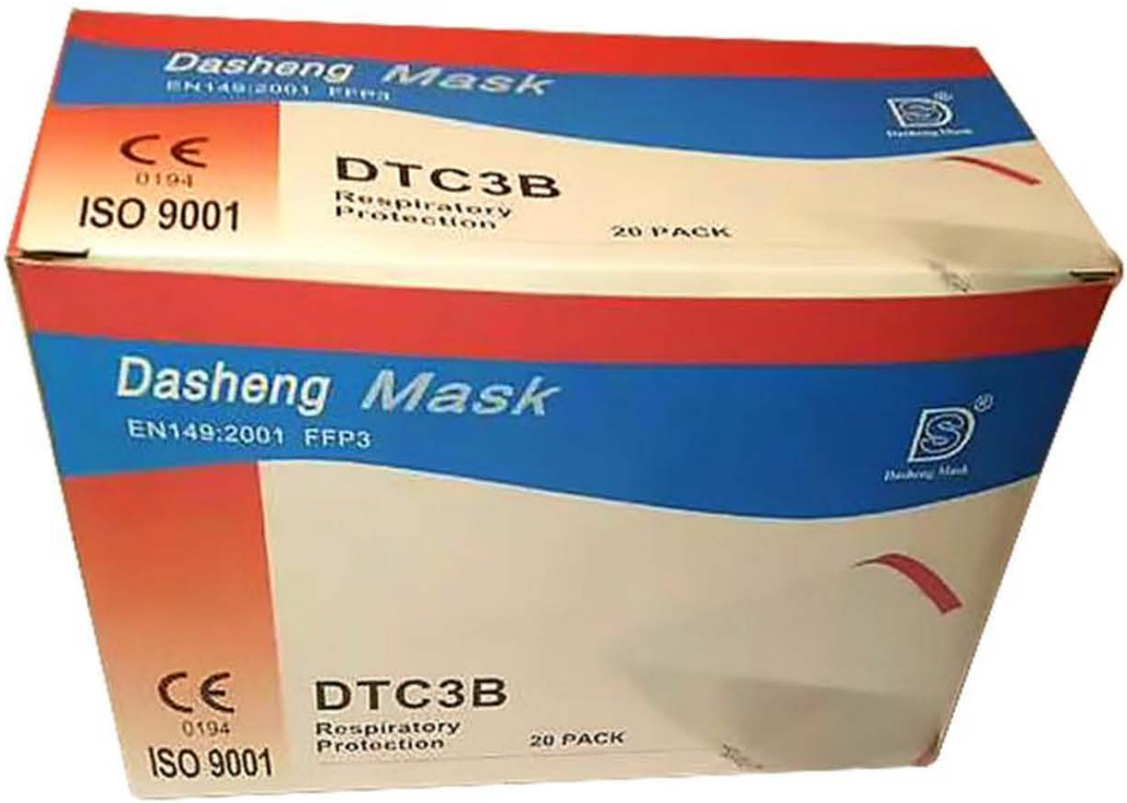
Package: DTC3B (No Valve): 20 pcs / box, 20 boxs / carton = 400 pcs
(50cm x 40cm x 30cm, about 6KG).

DTC3B-F (With Valve): 10 pcs / box, 20 boxs / carton = 200 pcs
(50cm x 40cm x 30cm, about 5KG).

European Packaging

Note. US FDA Compliance Labelling/ Packaging

US N95 NIOSH FDA510K Model: DTC3B 84A-4336
CDC: 86-21-5778-3126



European Packaging

Note. US FDA Compliance Labelling/ Packaging

US N95 NIOSH FDA510K Model: DTC3B 84A-4336
CDC: 86-21-5778-3126

Surgical N95s Respirator Mask

Material: SMMMS multilayer structure, the inner and outer layers are spunbond non-woven fabrics, and the middle layer is meltblown fabrics.

Explain: Optional valve, headband, built-in nose clip, duckbill-shaped facial structure help reduce fogging.

European Packaging

Note. US FDA Compliance Labelling/ Packaging

US N95 NIOSH FDA510K Model: DTC3B 84A-4336
CDC: 86-21-5778-3126

Nothing is more important than breathing Dasheng

Remarks: Non-sterile. United States and European double standard products.

European Packaging

US N95 NIOSH FDA510K Model: DTC3B-F 84A-4471
Alternative Surgical Value Ventilator
CDC: 86-21-5778-3126

International Organization for Standardization ISO 13485

INTERNATIONAL CERTIFICATIONS ISO 9001

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Certification: CDC-NIOSH-FDA / Surgical N95 (DTC3B: TC-84A-4336
CDC-NIOSH / N95 (DTC3B-F: TC-84A-4471)

European Packaging

US N95 NIOSH FDA510K Model: DTC3B 84A-4336
CDC: 86-21-5778-3126

International Organization for Standardization ISO 13485

INTERNATIONAL CERTIFICATIONS ISO 9001

Cone Surgical N95s
Surgical N95s Respirator Mask

Material: SMMMS multilayer structure, the inner and outer layers are spunbond non-woven fabrics, and the middle layer is meltblown fabrics.

Package: DTC3M-1 (No Valve): 20 pcs / box, 20 boxs / carton = 400 pcs (70cm x 30cm x 35cm, about 6KG).

DTC3M-1F (With Valve): 10 pcs / box, 20 boxs / carton = 200 pcs (70cm x 30cm x 35cm, about 4.5KG).

Explain: Optional valve, headband, curved nose clip, easy to maintain shape, not easy to collapse.

Certification: CDC-NIOSH-FDA / Surgical N95 (DTC3M-1: TC-84A-4331),

Remarks: Non-sterile. United States and European double standard products.

US N95 NIOSH FDA510K Model: DTC3M-1 84A-4331
CDC: 86-21-5778-3126

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Vertical-Fold Flat Surgical N95s Surgical and flat Surgical N95s Respirator Mask

Material: SMMMS multilayer structure, the inner and outer layers are spunbond non-woven fabrics, and the middle layer is meltblown fabrics.

DTC3X (No Valve): 20 pcs / box, 20 boxs / carton = 400 pcs (60cm x 30cm x 35cm, about 6KG).

DTC3X-F (With Valve): 10 pcs / box, 20 boxs / carton = 200 pcs (60cm x 30cm x 35cm, about 4.5KG).

Explain: Optional valve, headband, curved nose clip, easy to maintain shape, not easy to collapse.

CDC-NIOSH / N95 (DTC3X: TC-84A-4329 / DTC3X-F: TC-84A-4472),

Remarks: Non-sterile. United States and European double standard products.

US N95 NIOSH FDA510K Model: DTC3X: TC-84A-4329 Alt. DTC3X-1 878-4040
CDC: 86-21-5778-3126

International Organization for Standardization ISO 13485

INTERNATIONAL CERTIFICATIONS ISO 9001

US N95 NIOSH FDA510K Model: DTC3X: TC-84A-4329 Alt.
DTC3X-1 878-4040
CDC: 86-21-5778-3126

US N95 NIOSH FDA510K Model: DTC3X: TC-84A-4329 Alt.
DTC3X-1 878-4040
CDC: 86-21-5778-3126

US N95 NIOSH FDA510K Model: DTC3X: TC-84A-4329 Alt.
DTC3X-1 878-4040
CDC: 86-21-5778-3126

Shanghai Dasheng Health Products Manufacture Co.,Ltd

Donning & Fitting Instructions:
To be followed each time respirator is worn.

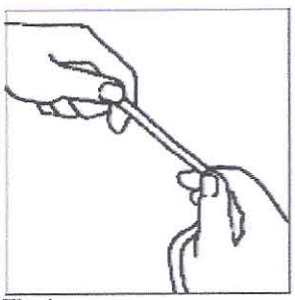
Fig. 1

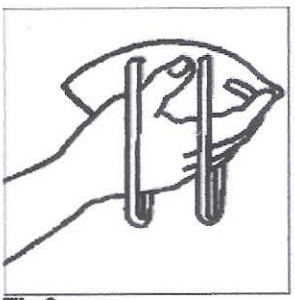
Fig. 2


Fig. 3


Fig. 4


Fig. 5

1. Prestretch top and bottom straps before placing respirator on the face
2. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.
3. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it high at the top back of your head. Pull the bottom strap over your head and position it around the neck below the ears.
4. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece. Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance.
5. Use two hands perform a user seal check prior to each wearing. To check fit, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step. If air leaks at the respirator edges, work the straps back along the sides of your head.

If you CANNOT achieve a proper fit, DO NOT enter the contaminated area. See your supervisor or Call 0086-21-57783029 Shanghai Dasheng Health Products Mnaufacture Co.,Ltd for proper fitting.


20
YEARS
1997-2017
Dasheng