

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

CE

INSPEC International Ltd, 81 Leake Height Way, Salford, Manchester, M6 9LJ, England, United Kingdom (UK)

The certificate has been issued in conformity with the standards and conditions set out in INSPEC's Regulations and Conditions of Use. Inspectors are not responsible for the use of the certificate or the product. The certificate is not to be used for any other purpose.

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INSPEC

Certificate Number: PFC18161085

Product details

Model identification:

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

Key: **NR** Not in conformity / limited to single shift use only
D Exhalation valve, requirements satisfied

Technical file reference: DTF 9 (1718161085)

Test reports: 07.03.71, 07.04.36, 07.06.33, 07.06.34, 08.11.03 & 1.11.01.21

Category: B
Category B 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

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Current Issue: 10/2019

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Certificate Number: PFC18161085

Certificate amendment record

Date	Description
10/02/2019	Initial issue

Conditions attached to the issue of this certificate:

- 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 appropriate to the country where the product is to be sold.
- Any changes to the product, technical file or quality management plan, shall be immediately notified to INSPEC.
- The Manufacturer/Authorised Representative shall comply at all times with INSPEC's Regulations governing CE Product Certification.
- Satisfactory maintenance of certification against module C2 or Module D for category B product.
- This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.
- The 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.

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Current Issue: 10/2019

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INSPEC

Certificate Number: PPE18161037

Certificate amendment record

Date	Description
23 October 2018	AMENDMENT PPE2 NR due to type
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/Authorized 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 management plan shall be immediately notified to INSPEC.
3. The Manufacturer/Authorized 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.
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INSPEC International Ltd, 16 Ladbroke Grove, London, W8 3LA, England. Registered Office: 16 Ladbroke Grove, London, W8 3LA, England.

This certificate has been issued in accordance with the provisions of the European Union's CE Marking Regulations and is subject to the conditions of use set out in the certificate holder's terms and conditions of business.

Current Issue: 03/10/18

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2-3 DTC3X



CE 认证：

 DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

Food and Drug Administration
Center for Drug Evaluation and Research
Washington, DC 20205

APR 9 7 2009

Ms. Maggie Zheng
National Health Products
Number 228 West Road Zhongshan Street
Shanghai, CHINA

Re: K006141
Trade/Device Name: D05 N95 NIOSH Mask and Flat Respirator Masks for Single Use
Regulation Number: 21 CFR 804.6040
Regulatory Classification: Surgical Appliance
Regulatory Class: II
Product Code: 6040, PCC
Date: April 8, 2009
Expiration: April 15, 2009

Dear Ms. Zheng:

Notice of your recent Section 510(b) premarket notification of intent to market the device submitted and how we determined the device is substantially equivalent to the predicate device is in the enclosed letter. The enclosed letter also contains information to assist in interstate commerce from May 19, 2009, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (the Act) that no longer require a premarket approval application (PMA). You may, therefore, market the device, subject to the provisions of the Federal Food, Drug, and Cosmetic Act (which do not require approval of a premarket approval application (PMA)). You may, therefore, market the device, subject to the provisions of the Federal Food, Drug, and Cosmetic Act (which do not require approval of a premarket approval application (PMA)).

If your device is classified into one or more other class II (Special Controls) or class III (PMA), you will submit to FDA, a complete premarket notification application (PMNA) or PMA, respectively, to the FDA, in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act (which do not require approval of a premarket approval application (PMA)).

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 statute 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 Ranner, 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

Enclosures




INDICATIONS FOR USE

FIRM/NAME OF KNOWN: K9C931
APPLICANT: Shanghai Deyang Health Products Manufacturing Co., Ltd.
DEVICE NAME:
DS N90 Surgical Masks and Flat Surgical Masks for single use
DS NR: DS N90 Surgical Mask
DS Description:
DS (N90) Non-Leak Mouthpiece: DS-RTD8, DS-PH67, DS-GS224, DS-HB57, DS-MB57, DS-JW57, DS-TCR3, DS-TCR3A, DS-TCR3B, DS-TCR3C, DS-TCR3D, DS-TCR3E, DS-TCR3F, DS-TCR3G, DS-TCR3H, DS-TCR3I, DS-TCR3J, DS-TCR3K, DS-TCR3L, DS-TCR3M, DS-TCR3N, DS-TCR3O, DS-TCR3P, DS-TCR3Q, DS-TCR3R, DS-TCR3S, DS-TCR3T, DS-TCR3U, DS-TCR3V, DS-TCR3W, DS-TCR3X, DS-TCR3Y, DS-TCR3Z, DS-TCR3AA, DS-TCR3AB, DS-TCR3AC, DS-TCR3AD, DS-TCR3AE, DS-TCR3AF, DS-TCR3AG, DS-TCR3AH, DS-TCR3AI, DS-TCR3AJ, DS-TCR3AK, DS-TCR3AL, DS-TCR3AM, DS-TCR3AN, DS-TCR3AO, DS-TCR3AP, DS-TCR3AQ, DS-TCR3AR, DS-TCR3AS, DS-TCR3AT, DS-TCR3AU, DS-TCR3AV, DS-TCR3AW, DS-TCR3AX, DS-TCR3AY, DS-TCR3AZ, DS-TCR3BA, DS-TCR3BB, DS-TCR3BC, DS-TCR3BD, DS-TCR3BE, DS-TCR3BF, DS-TCR3BG, DS-TCR3BH, DS-TCR3BI, DS-TCR3BJ, DS-TCR3BK, DS-TCR3BL, DS-TCR3BM, DS-TCR3BN, DS-TCR3BO, DS-TCR3BP, DS-TCR3BQ, DS-TCR3BR, DS-TCR3BS, DS-TCR3BT, DS-TCR3BU, DS-TCR3BV, DS-TCR3BW, DS-TCR3BX, DS-TCR3BY, DS-TCR3BZ, DS-TCR3CA, DS-TCR3CB, DS-TCR3CC, DS-TCR3CD, DS-TCR3CE, DS-TCR3CF, DS-TCR3CG, DS-TCR3CH, DS-TCR3CI, DS-TCR3CJ, DS-TCR3CK, DS-TCR3CL, DS-TCR3CM, DS-TCR3CN, DS-TCR3CO, DS-TCR3CP, DS-TCR3CQ, DS-TCR3CR, DS-TCR3CS, DS-TCR3CT, DS-TCR3CU, DS-TCR3CV, DS-TCR3CW, DS-TCR3CX, DS-TCR3CY, DS-TCR3CZ, DS-TCR3DA, DS-TCR3DB, DS-TCR3DC, DS-TCR3DD, DS-TCR3DE, DS-TCR3DF, DS-TCR3DG, DS-TCR3DH, DS-TCR3DI, DS-TCR3DJ, DS-TCR3DK, DS-TCR3DL, DS-TCR3DM, DS-TCR3DN, DS-TCR3DO, DS-TCR3DP, DS-TCR3DQ, DS-TCR3DR, DS-TCR3DS, DS-TCR3DT, DS-TCR3DU, DS-TCR3DV, DS-TCR3DW, DS-TCR3DX, DS-TCR3DY, DS-TCR3DZ, DS-TCR3EA, DS-TCR3EB, DS-TCR3EC, DS-TCR3ED, DS-TCR3EE, DS-TCR3EF, DS-TCR3EG, DS-TCR3EH, DS-TCR3EI, DS-TCR3EJ, DS-TCR3EK, DS-TCR3EL, DS-TCR3EM, DS-TCR3EN, DS-TCR3EO, DS-TCR3EP, DS-TCR3EQ, DS-TCR3ER, DS-TCR3ES, DS-TCR3ET, DS-TCR3EU, DS-TCR3EV, DS-TCR3EW, DS-TCR3EX, DS-TCR3EY, DS-TCR3EZ, DS-TCR3FA, DS-TCR3FB, DS-TCR3FC, DS-TCR3FD, DS-TCR3FE, DS-TCR3FF, DS-TCR3FG, DS-TCR3FH, DS-TCR3FI, DS-TCR3FJ, DS-TCR3FK, DS-TCR3FL, DS-TCR3FM, DS-TCR3FN, DS-TCR3FO, DS-TCR3FP, DS-TCR3FQ, DS-TCR3FR, DS-TCR3FS, 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DS-TCR3TU, DS-TCR3TV, DS-TCR3TW, DS-TCR3TX, DS-TCR3TY, DS-TCR3TZ, DS-TCR3UA, DS-TCR3UB, DS-TCR3UC, DS-TCR3UD, DS-TCR3UE, DS-TCR3UF, DS-TCR3UG, DS-TCR3UH, DS-TCR3UI, DS-TCR3UJ, DS-TCR3

Concurrence of CD821, Office of Device Evaluation (ODE)

John H. M. [Signature]
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
SIS(K) Number: K 090131

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 <p>NELSON LABORATORIES</p> <p>FBIAL REPORT</p> <p>BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE</p> <p>PROCEDURE NO. STP0054 REV 02</p> <p>LABORATORY NO. 44876</p>	 <p>BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE</p> <p>LABORATORY NUMBER: PROCEDURE NUMBER:</p> <p>SAMPLE SOURCE:</p> <p>SAMPLE IDENTIFICATION: DEVIATION:</p> <p>SAMPLE RECEIVED DATE:</p> <p>LAB PHASE START DATE:</p> <p>LAB PHASE COMPLETION DATE:</p> <p>REPORT ISSUE DATE:</p>	<p>44876 STP004 REV 03 Shanghai Dashing Health Products Manufacturer Co., Ltd Manufacturing Co., Ltd Water in Tabeles 1-3</p> <p>07/24/2009 03/30/2009 07/24/2009 07/24/2009 07/24/2009</p>	 <p>Bacterial Filtration Efficiency and Differential Pressure</p> <p>Shanghai Dashing Health Products Manufacturer Co., Ltd Lab Number 44876</p> <p>SAMPLE PREPARATION:</p> <p>BFE test samples were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity prior to testing.</p> <p>TEST PROCEDURE:</p> <p>A culture of Staphylococcus aureus, ATCC #6538, was diluted in 1.5% peptone water (PPW) to a precise concentration to yield challenge level counts of 2200 ± 500 CFU per test sample. Two bacterial cultures were then pumped through a Chamber radipore at a controlled flow rate and fixed pressure. The challenge challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPPS of approximately 3.2 µm. Two hundred and twenty (200) µl of the challenge suspension was drawn through a 0.45 µm, saline, viable pore, Andersen sampler for collection. The collection flow rate using the test sample and Andersen sampler was maintained at 25 L/min 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.</p> <p>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 material in the stream) and reference control were included after 5-10 test samples. The Andersen sampler, a glass sampler, employed the aerosol droplets onto six upstream canisters digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 2-4 hours. Colonies formed by each bacteria factor Andersen sampler were counted and correlated to probable values using the dilution factor. The average challenge level was calculated. These correlated counts were used to determine the average challenge level delivered to the test sample. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPPS of the challenge aerosol.</p> <p>The AP test cups measured the differential air pressure on both sides of the test sample using an incline, 1/2" bore, or digital manometer. Testing was conducted at a flow rate of 8 L/min (columetric).</p> <p>RESULTS:</p> <p>The results are summarized in Tables 1-3.</p>
<p>PREPARED FOR:</p> <p>SHANGHAI DASHING HEALTH PRODUCTS MANUFACTURER CO., LTD</p> <p>NO. 228 SHAN ROAD</p> <p>ZHONGSHAN DIST. SHANGHAI DISTRICT</p> <p>SHANGHAI 201813</p> <p>P.R. CHINA</p>	<p>INTRODUCTION:</p> <p>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 efficiency (BPBE). This procedure provides for more stress challenges to more filtration materials than would be expected in normal use. This procedure addresses a representative challenge to be delivered to test materials. This method complies with ASTM F2743.</p> <p>The differential pressure (DP) or Delta P test determined the air challenge differential of the aerosol materials. This technique involved a single atmospheric or static pressure atmosphere 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.</p> <p>ACCEPTANCE CRITERIA</p> <p>The BFE control average must be 2200 ± 500 colony forming units (CFU). A BFE test with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 2900, will be an acceptable. Acceptance of tests with control averages exceeding 2700 shall be at the sponsor's approval.</p> <p>The mean particle size (MPPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 µm.</p> <p>The average BPBE or BFE the reference material must be within the upper and lower control limits established for the BFE test.</p> <p>The average Delta P must be the reference material must be within the upper and lower control limits established for the Delta P test.</p>	<p>44876 STP004 REV 03 Shanghai Dashing Health Products Manufacturer Co., Ltd Manufacturing Co., Ltd Water in Tabeles 1-3</p> <p>07/24/2009 03/30/2009 07/24/2009 07/24/2009 07/24/2009</p>	<p>44876 STP004 REV 03 Shanghai Dashing Health Products Manufacturer Co., Ltd Manufacturing Co., Ltd Water in Tabeles 1-3</p> <p>07/24/2009 03/30/2009 07/24/2009 07/24/2009 07/24/2009</p>
<p>SUBMITTED BY:</p> <p>NELSON LABORATORIES, INC.</p> <p>530 S. REDWOOD RD.</p> <p>SALT LAKE CITY UT 84124-6003</p> <p>801-526-7560</p> <p>Page 1 of 8</p>	<p>Page 2 of 8</p>	<p>Page 3 of 8</p>	<p>Page 3 of 8</p>

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Lab Number 446576

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

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

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

The ΔP values were reported in mm water* at test area and calculated using the following equation:

$$\Delta P = \frac{Q}{\text{Test Area}}$$

Where: Q = 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 reported in control charts. The individual ΔP values must be within the upper and lower control limits (±3 standard deviations) for the test. Testing that the acceptance criteria previously stated in this report.

STATEMENT OF UNCERTAINTY:
If applicable, the statement of uncertainty is available to sponsors upon request.

Shen Guoli 12 Dec 2006
Study Director Study Completion Date

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TABLE 1. Results
Sample Identification: DS Cuped Surgical Mask

UNIT NUMBER	ΔP (mm H ₂ O/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: 2.8 μm

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

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TABLE 2. Results
Sample Identification: DS Folded Surgical Mask

UNIT NUMBER	ΔP (mm H ₂ O/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: 2.8 μm

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

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TABLE 3. Results
Sample Identification: DS Flat Surgical Mask

UNIT NUMBER	ΔP (mm H ₂ O/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: 2.8 μm

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

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NIOSH 认证：

DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-14513
Mfr Reference: SDDTDCXAF-2

Public Health Service
Division for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 12071
Pittsburgh, PA 15212-0070
Phone: 412-385-4000
Fax: 412-385-4051
July 20, 2006

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 DTCXN N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Daxing Health Products Manufacturer Co. Quality Manual, Edition B, dated May 10, 2005.

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-844-4-029 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 84.4(a) and on the basis 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
Heinz W. Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

澳洲资质：

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