# 仙桃志博无纺布制品有限公司

# ABOUT US

- Xian Tao Zhibo Non-woven Products Co.,Ltd is founded on 2008. Located in Xian Tao City, China. The city is famous in non-woven fabric products all over the world. We are specialized in disposable medical nonwoven products which are used in medical area, personal protecting Area. All product are certify by CE/ISO.

页码，1/1(W)

# 营业执照

统一社会信用代码 91429004550667264H

| | |
|---|---|
| 名　　称 | 仙桃市志博无纺布制品有限公司 |
| 类　　型 | 有限责任公司(自然人投资或控股) |
| 住　　所 | 仙桃市彭场镇禾丰小区8号 |
| 法定代表人 | 赵志勇 |
| 注册资本 | 壹佰万圆整 |
| 成立日期 | 2010年02月05日 |
| 营业期限 | 长期 |
| 经营范围 | 塑料制品、无纺布制品、纱布制品的加工销售；无纺布设备及配件的销售；纱线纺织、印花；经营货物进出口、技术进出口（法律、行政法规禁止的项目除外；法律、行政法规限制的项目取得许可后方可经营） |

登记机关 仙桃市工商行政管理局

年　月　日

2018　12　26

企业信用信息公示系统网址：http://hb.gsxt.gov.cn

中华人民共和国国家工商行政管理总局监制

http://192.0.99.148/TopIcis/CertificatePrint.do

2018/12/28

# BUSINESS LICENSE

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIF

**Fiscal Year 2020**
**CERTIFICATION OF REGISTRATION**

This certifies that:

**Xiantao Zhibo Nonwoven Products Co., Ltd**
**No.8, Hefeng Industrial Zone, Pengchang Town Xiantao City, Hubei Province, 430000, China.**

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

**Registration Number: 3013580507**
**Device Listing#: See annex**

*SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.*

Sungo global service FDA

SUNGO
Executive Director
Issued: Oct. 25 2019
Cert. No.: 20060S304555
Expiration Date: Dec. 31 2020
CERTIFIED

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shage2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

# FDA REGISTRATION

# POSI CERTIFICATE

CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE ◆ 认证证书

POSI

CERTIFICATE

Hereby certifies that

**Xiantao Zhibo Non-woven Products Co., Ltd.**

Business license number: 91429004550667264H
Registered Address: No. 8 Hefeng Industrial Park, Pengchang Town, Xiantao City, Hubei Province.China
Audit Address: No. 8 Hefeng Industrial Park, Pengchang Town, Xiantao City, Hubei Province.China

HAS ESTABLISHED AND APPLIED A QUALITY MANAGEMENT SYSTEM FOR:

The Production and Sales of Non-sterilized Non-woven Protective Products (Masks, Caps, Clothes, Shoe Cover, Pillow Case, Bed Sheet, Apron, Sleeve Cover, Beard Net)(Export Only); The Sales of Plastic Film Protective Products (Shoe Cover, Sleeve Cover, Caps, Apron and CPE Robe) (Export Only)

AN AUDIT WAS PERFORMED, PROOF HAS BEEN FURNISHED THAT THE REQUIREMENTS ACCORDING TO

**GB/T19001-2016/ISO9001:2015**

are fulfilled

This certificate is issued by Shanghai POSI certification Co., Ltd., the certificate holder shall accept the surveillance audit by POSI. For obtaining the validity of certificate, please visit http://www.posicert.com, the certificate information is also available on the CNCA official website: http://cx.cnca.cn.

SHANGHAI POSI CERTIFICATION CO.,LTD POSI 波西认证

General Manager

Certificate Registration No：POSIQ00033
Initial issue date：2019.07.10 Issue date：2019.07.10 Valid until: 2022.07.09

Shanghai POSI Certification Co., Ltd.
Room 1002A, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE ◆ 认证证书

POSI

CERTIFICATE

Hereby certifies that

**Xiantao Zhibo Non-woven Products Co., Ltd.**

Business license number: 91429004550667264H
Registered Address: No. 8 Hefeng Industrial Park, Pengchang Town, Xiantao City, Hubei Province.China
Audit Address: No. 8 Hefeng Industrial Park, Pengchang Town, Xiantao City, Hubei Province.China

HAS ESTABLISHED AND APPLIED A QUALITY MANAGEMENT SYSTEM FOR:

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AN AUDIT WAS PERFORMED, PROOF HAS BEEN FURNISHED THAT THE REQUIREMENTS ACCORDING TO

**ISO13485:2016**

are fulfilled

This certificate is issued by Shanghai POSI certification Co., Ltd., the certificate holder shall accept the surveillance audit by POSI. For obtaining the validity of certificate, please visit http://www.posicert.com, the certificate information is also available on the CNCA official website: http://cx.cnca.cn.

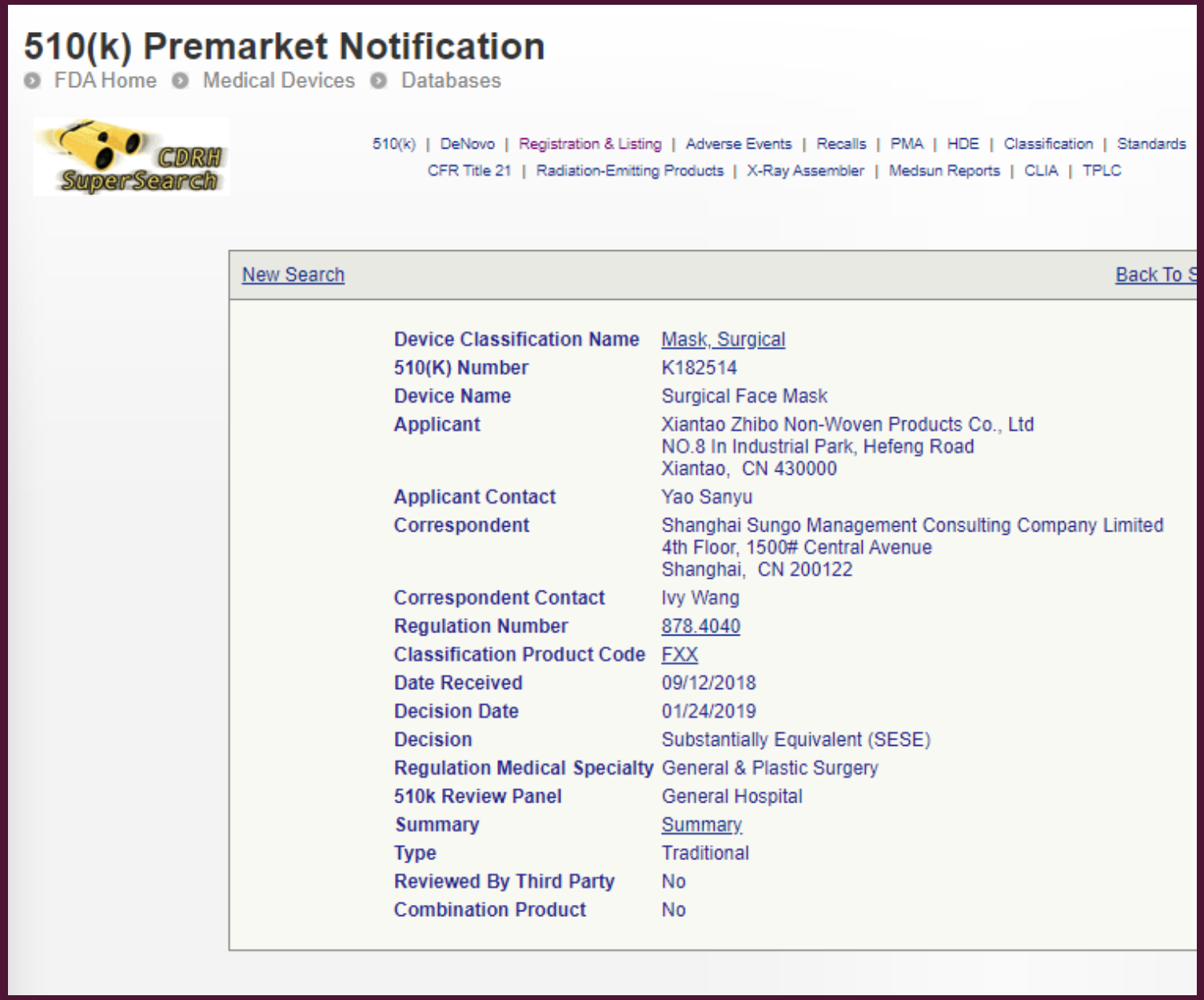
SHANGHAI POSI CERTIFICATION CO.,LTD POSI 波西认证

General Manager

Certificate Registration No：POSIMD00046
Initial issue date：2019.07.10 Issue date：2019.07.10 Valid until: 2022.07.09

Shanghai POSI Certification Co., Ltd.
Room 1002A, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

# 510(K) PREMARKET NOTIFICATION



## 510(k) Premarket Notification

FDA Home › Medical Devices › Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To S

| | |
|---|---|
| **Device Classification Name** | Mask, Surgical |
| **510(K) Number** | K182514 |
| **Device Name** | Surgical Face Mask |
| **Applicant** | Xiantao Zhibo Non-Woven Products Co., Ltd<br>NO.8 In Industrial Park, Hefeng Road<br>Xiantao, CN 430000 |
| **Applicant Contact** | Yao Sanyu |
| **Correspondent** | Shanghai Sungo Management Consulting Company Limited<br>4th Floor, 1500# Central Avenue<br>Shanghai, CN 200122 |
| **Correspondent Contact** | Ivy Wang |
| **Regulation Number** | 878.4040 |
| **Classification Product Code** | FXX |
| **Date Received** | 09/12/2018 |
| **Decision Date** | 01/24/2019 |
| **Decision** | Substantially Equivalent (SESE) |
| **Regulation Medical Specialty** | General & Plastic Surgery |
| **510k Review Panel** | General Hospital |
| **Summary** | Summary |
| **Type** | Traditional |
| **Reviewed By Third Party** | No |
| **Combination Product** | No |

**Annex to Report (No. 02650 )**

**Xiantao Zhibo Non-woven Products Co.,Ltd.**

| Product Name | Type |
|---|---|
| Cap | (18" 19" 21"), (9g -- 30g), (Single elastic Double elastic) |
| Face Mask | (18+20+25g), (20+20+25g), (14.5cm-17.5cm*9cm-9.5cm), (With valve /Without valve) |
| Sleeve Cover | 20cm*40cm, 22cm*46cm |
| Shoe Cover | 15cm*36cm, 16cm*38cm, 15cm*40cm, 1.5g--55g |
| Boot Cover | S, M, L, XL, 48cm*38cm, 48cm*42cm |
| Gloves | S, M, L, XL |
| Apron | S, M, L, XL, XXL, XXXL, XXXXL, 24"x42", 28"x46" |
| Isolation Gown | S, M, L, XL, XXL, XXXL, XXXXL |
| Surgical Gown | S, M, L, XL, XXL, XXXL, XXXXL |
| Bed Sheet | 120cm*180cm, 120cm*220cm, 120cm*240cm |
| Pillow Cases | 80cm*120cm, 53cm*76cm |
| Clothing/Dress/Suit | S, M, L, XL, XXL, XXXL, XXXXL |

This annex is only valid if attached to the report mentioned above.



**Compliance Report**

Applicant: Xiantao Zhibo Non-woven Products Co.,Ltd.
Address: NO.8 in Industrial Park Hefeng Road.Xiantao City, Hubei, China.

Product: Cap, Face Mask, Sleeve Cover, Shoe Cover, Boot Cover, Gloves, Apron, Isolation Gown, Surgical Gown, Bed Sheet, Pillow Cases, Clothing/Dress/Suit
Type: See annex for details

Product Classification: Class I

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **02650**
Initial Issue Date: **20 Feb 2017**

Tony Chen

General Manager (Signature)



# NQA COMPLIANCE REPORT

# PRODUCT ASSURANCE

OUR PRODUCT ARE TESTED BY CERTIFIED LAB(NELSON, SGS, NATIONAL STANDARD TEST CENTER)

NELSON LABORATORIES

Sponsor:
Yao Sanyu
Xiantao Zhibo Non-woven Products Co Ltd
DNO.8 Industrial Park Hefeng Rd.
Xiantao City, Hubei
Xiantao, 433000
CHINA

## Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article: LOT: 20170602
Study Number: 973405-S01
Study Received Date: 27 Jun 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: 800-STP0036 Rev 14
Customer Specification Sheet (CSS) Number:201704309 Rev 01

**Summary:** The testing was conducted in accordance with EN 14683:2014, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a validated software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

**Results:**

| Unit Number | Weight (g) | Aerobic | Fungal | Total Bioburden (CFU/mask) | Total Bioburden (CFU/g) |
|---|---|---|---|---|---|
| 1 | 2.8 | 478 | 34[a] | 511.7 | 182.7 |
| 2 | 2.7 | 325 | 15[a] | 339.6 | 125.8 |
| 3 | 2.8 | 71 | 21[a] | 92.0 | 32.8 |
| 4 | 2.7 | 41 | 6[a] | 47.0 | 17.4 |
| 5 | 2.8 | 37 | 6[a] | 42.4 | 15.1 |
| Recovery Efficiency | | | 66.7% | | |

Note: The results are reported as colony forming units (CFU) per mask.
Note: Sample positive testing was performed using *Bacillus atrophaeus*. The test article was not inhibitory using this test method.
[a] Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

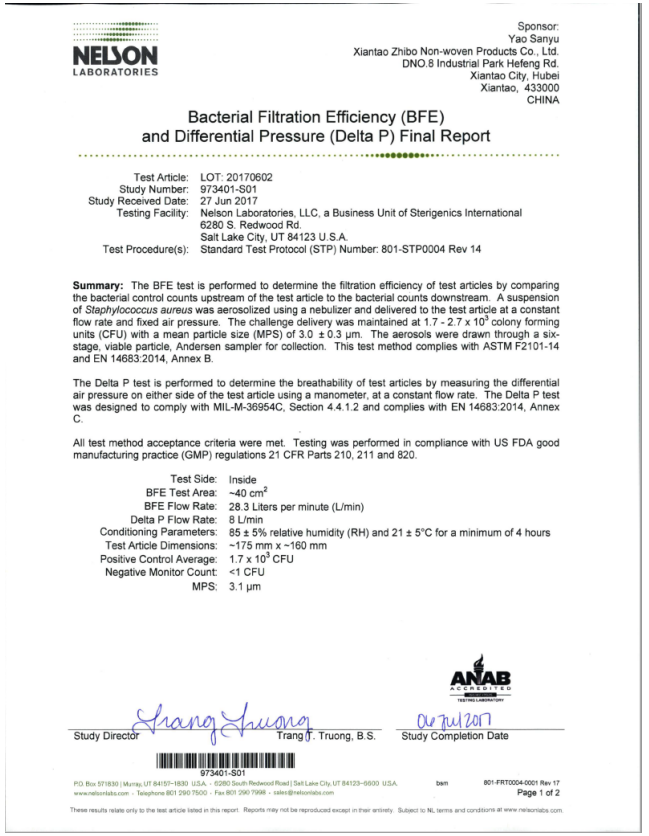
Study Director Robert J. Putnam, B.S. Study Completion Date

ANAB ACCREDITED TESTING LABORATORY

973405-S01







NELSON LABORATORIES

Sponsor:
Yao Sanyu
Xiantao Zhibo Non-woven Products Co., Ltd.
DNO.8 Industrial Park Hefeng Rd.
Xiantao City, Hubei
Xiantao, 433000
CHINA

## Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: LOT: 20170602
Study Number: 973401-S01
Study Received Date: 27 Jun 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

**Summary:** The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x $10^3$ colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Test Area: ~40 $cm^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions: ~175 mm x ~160 mm
Positive Control Average: 1.7 x $10^3$ CFU
Negative Monitor Count: <1 CFU
MPS: 3.1 µm

Study Director Trang T. Truong, B.S. Study Completion Date

ANAB ACCREDITED TESTING LABORATORY

973401-S01

# PRODUCTION

# STORAGE & INVENTORY