普尔德

Sino Protection

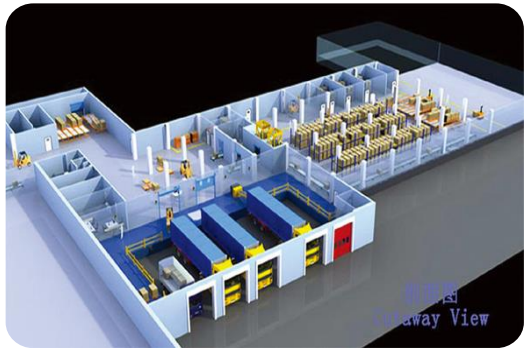
Sino Protection(Hefei) Medical Products Co., Ltd

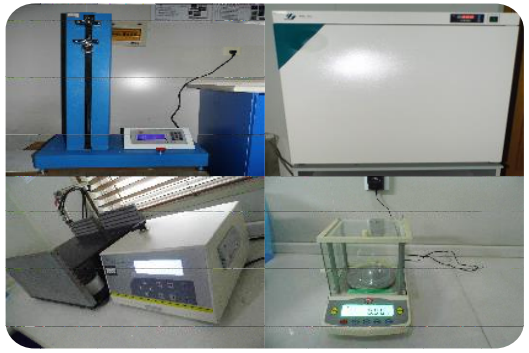
Company Introduction

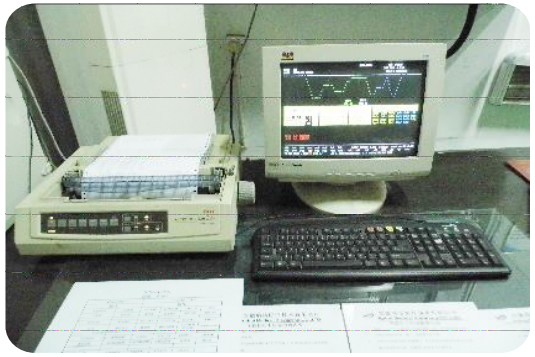
- Since 1999, after 20 years of development, Sino has become the leader in non-woven material field. The turnover has reached to $200 millions in 2019.
- The headquarter located in Hefei, China, now has 6 factories in China; total employees over 3000;
- In 2019, we have invested a new plant in Myanmar, is going to start the production in Dec of 2019. The plant will focus to produce the surgical gowns and surgical drapes;
- Main customers are all from US, Europe and Japan, most are in the top position in medical circle, such as Dupont，3M, MEDLINE etc




ETO STERILIZATION

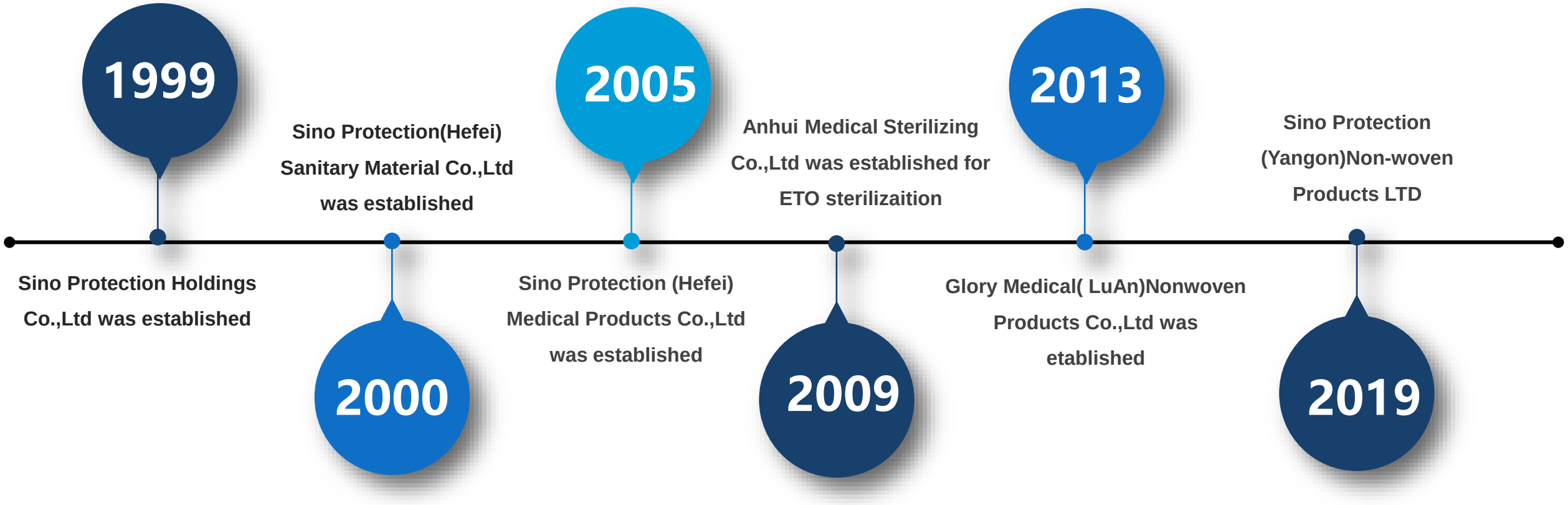






- AMSC mainly works on the ETO sterilization field. In plant, there is a 110 m^3 chamber manufactured by Vacudyne in USA and two advanced domestic chambers. Monthly output is 9000m^3
- Standard management is adopted by AMSC, the whole sterilization process consists of precondition sterilization, aeration etc. Sterilization process monitored by automatic control system from beginning to end is implemented according to the requirements of EU Standard and United States Standard strictly

Company Histroy



Company Introduction

Main products

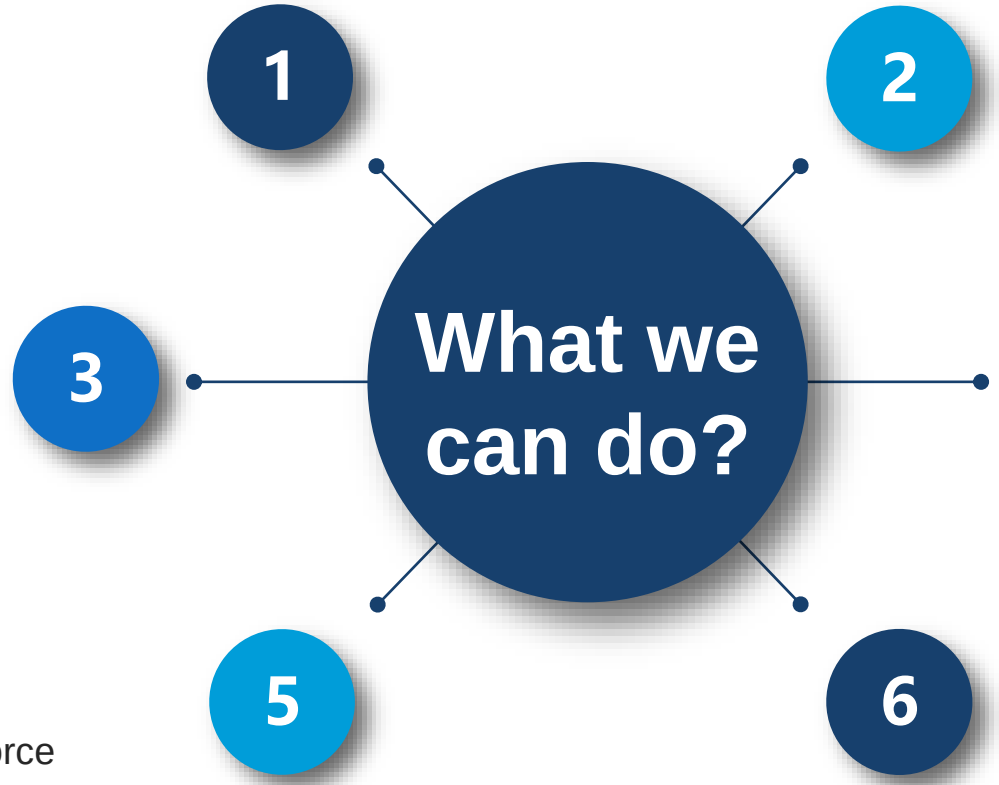
- surgical gown/Pack /drape
- Industries
- Raw Material
- Hand Towel/ Pouch
- Coveralls
- Mask

Quality system

- ISO13485: 2016 certificate
- Passed FDA auditing

Employee team

- Loyal, stable workforce
- Multi-functional workers combined with professional workers
- Continuous training model



Customer and market

The company's products are mainly sold to the United States, Europe, Japan and other places, and has established long-term cooperative relations with many foreign customers

Management team

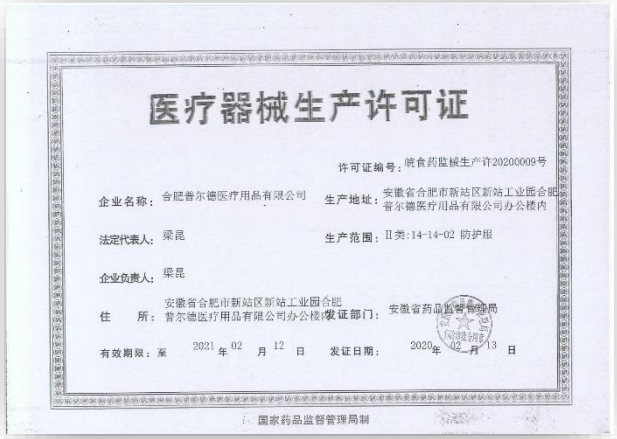
- Young, high-quality middle and senior management
- Experienced young managers team
- Learning Organization

Management mode

- Everything is customer-oriented and market-oriented, providing customers with satisfactory services and products.
- Flexible production line that responds quickly to market changes
- Statistical quality management model that is compatible with quality systems and regulations

Company Qualification

- National high and new technology enterprise
- The Anhui province quality management award
- The Anhui province import and export enterprise
- Anhui province medical equipment industry association, vice president group
- TUV ISO13485:2016,CE Certificated
- SGS industrial protection 11B certificated
- Medical equipment production license awarded by Anhui province food and drug administration
- Pass 3 times FDA audit in 2004,2014 and 2018; and 0 finding in 2018 audit.



Company Qualification

CE certification

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 02 62151 011

Manufacturer: **Sino Protection (Hefei) Medical Products Co., Ltd.**
Area B, Xinzhan Industrial Park
Xinghuo Road
230011 Hefei
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Surgical Gown, Surgical Drape, Surgical Pack, Coverall, Non-woven Swabs**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH17364EXT01

Valid from: 2017-04-25
Valid until: 2022-04-24

Date, 2017-03-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

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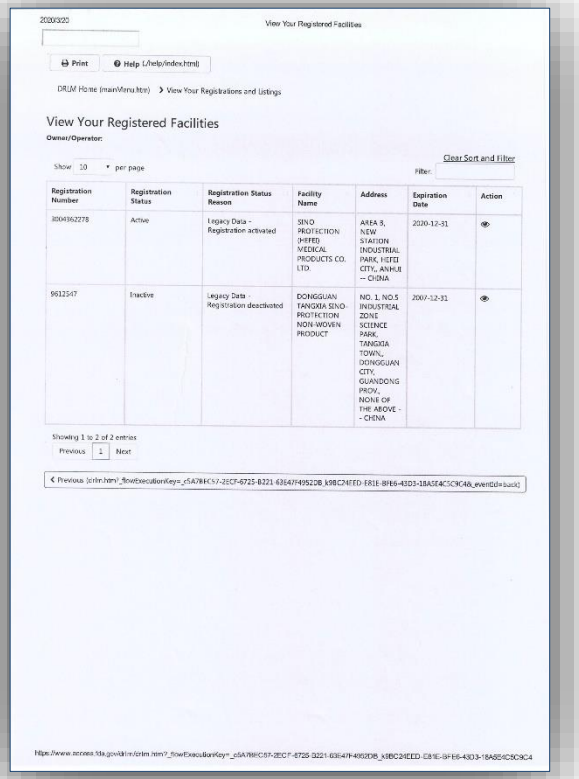
Company Qualification

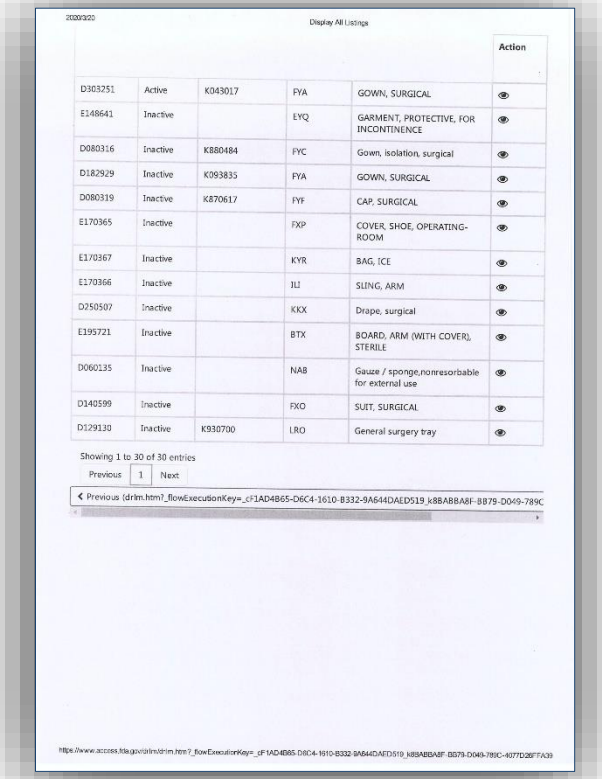
FDA REGISTRATION



View Your Registered Facilities

Owner/Operator:

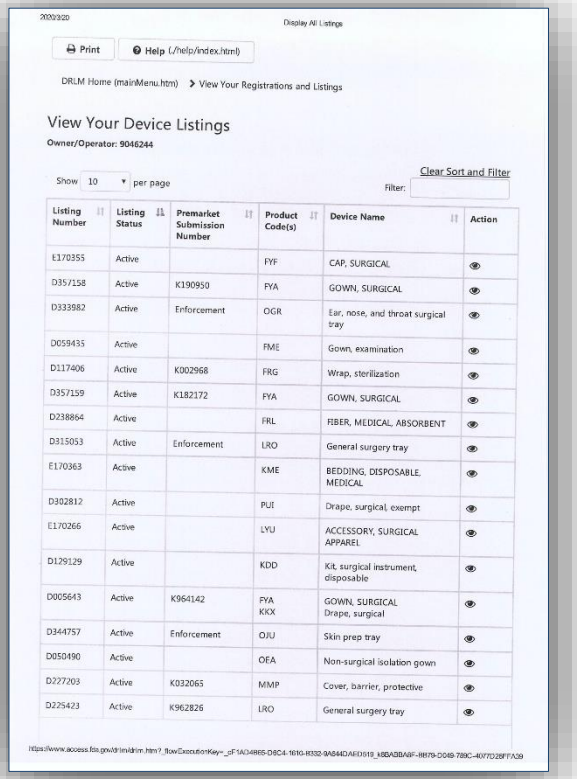
Registration Number	Registration Status	Registration Status Reason	Facility Name	Address	Expiration Date	Action
3004362278	Active	Legacy Data - Registration activated	SINO PROTECTION (HEFEI) MEDICAL PRODUCTS CO. LTD.	AREA B, NEW STATION INDUSTRIAL PARK, HEFEI CITY,, ANHUI -- CHINA	2020-12-31	
9612547	Inactive	Legacy Data - Registration deactivated	DONGGUAN TANGXIA SINO-PROTECTION NON-WOVEN PRODUCT	NO. 1, NO.5 INDUSTRIAL ZONE SCIENCE PARK, TANGXIA TOWN,, DONGGUAN CITY, GUANDONG PROV., NONE OF THE ABOVE -- CHINA	2007-12-31	



					Action
D303251	Active	K043017	FYA	GOWN, SURGICAL	
E148641	Inactive		EYQ	GARMENT, PROTECTIVE, FOR INCONTINENCE	
D080316	Inactive	K880484	FYC	Gown, isolation, surgical	
D182929	Inactive	K093835	FYA	GOWN, SURGICAL	
D080319	Inactive	K870617	FYF	CAP, SURGICAL	
E170365	Inactive		FXP	COVER, SHOE, OPERATING-ROOM	
E170367	Inactive		KYR	BAG, ICE	
E170366	Inactive		JLJ	SLING, ARM	
D250507	Inactive		KKX	Drape, surgical	
E195721	Inactive		BTX	BOARD, ARM (WITH COVER), STERILE	
D060135	Inactive		NAB	Gauze / sponge,nonresorbable for external use	
D140599	Inactive		FXO	SUIT, SURGICAL	
D129130	Inactive	K930700	LRO	General surgery tray	

Showing 1 to 30 of 30 entries

Previous 1 Next



View Your Device Listings

Owner/Operator: 9046244

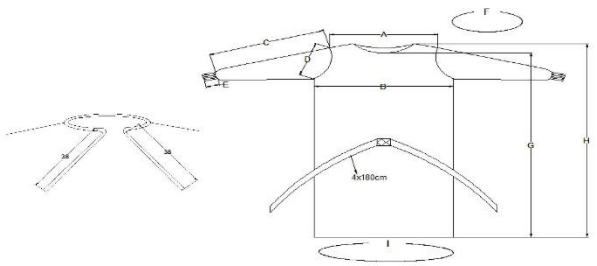
Listing Number	Listing Status	Premarket Submission Number	Product Code(s)	Device Name	Action
E170355	Active		FYF	CAP, SURGICAL	
D357158	Active	K190950	FYA	GOWN, SURGICAL	
D333982	Active	Enforcement	OGR	Ear, nose, and throat surgical tray	
D059435	Active		FME	Gown, examination	
D117406	Active	K002968	FRG	Wrap, sterilization	
D357159	Active	K182172	FYA	GOWN, SURGICAL	
D238864	Active		FRL	FIBER, MEDICAL, ABSORBENT	
D315053	Active	Enforcement	LRO	General surgery tray	
E170363	Active		KME	BEDDING, DISPOSABLE, MEDICAL	
D302812	Active		PUI	Drape, surgical, exempt	
E170266	Active		LYU	ACCESSORY, SURGICAL APPAREL	
D129129	Active		KDD	Kit, surgical instrument, disposable	
D005643	Active	K964142	FYA KKX	GOWN, SURGICAL Drape, surgical	
D344757	Active	Enforcement	OJU	Skin prep tray	
D050490	Active		OEA	Non-surgical isolation gown	
D227203	Active	K032065	MMP	Cover, barrier, protective	
D225423	Active	K962826	LRO	General surgery tray	

Isolation Gown

- Size: Universal
- Product: Isolation gown , 20001
- Material: PP+PE
- Package： 10pcs/bag 100pcs/case
- Case size： 60x40x36cm
- Weight: 11.4kg
- Scope: used for genreall isolation

Isolation Gown

1, Finished product （Unit：cm）



	Description	尺寸	Tolerance
A	shoulder	72	±2
B	chest	72	±2
C	Sleeve length	50	±2
D	Sleeve width	24	±2
E	Cuff	7	±1
F	Neck binding	62	±2
G	Front side to edge	110	±2
H	Total length	120	±2
I	width	155	±2

Material: 18gSPP+20g PE laminated yellow
Packaging: 10pcs/ bag ,bag size:38x58cm, 10bags/case ,case dimension:60x40x36cm

1/2

NELSON LABORATORIES

Sponsor:
Slinda Ma
Sino Protection Medical Products Co., Ltd.
Area B New Station Industrial Park
Hefei, Anhui, 230051
CHINA

ASTM Method F 1670 Synthetic Blood Penetration Final Report

Test Article: SPI-15-008
Purchase Order: 20160712
Study Number: 904721-S01
Study Received Date: 15 Jul 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0061 Rev 06

Summary: This test method was performed to evaluate the resistance of protective materials to penetration by synthetic blood under conditions of continuous liquid contact. Protective materials' pass/fail determinations are based on visual detection of synthetic blood penetration. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 30-80% relative humidity (RH) and then tested for liquid penetration using synthetic blood. The synthetic blood penetration method complies with ASTM F1670; sampling was at the discretion of the sponsor. 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.

Number of Test Articles Tested: 3
Number of Test Articles Passed: 3
Test Article Side Tested: Either Side
Test Article Preparation: Cut from the Material at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: A (No retaining screen)

Results:

Test Article Number	Synthetic Blood Penetration	Result
1-3	None Seen	Pass
Negative Control	None Seen	Acceptable
Positive Control	Yes	Acceptable

ANAB ACCREDITED TESTING LABORATORY

Study Director Jennifer Jorgenson, B.S.
25 Jul 2016 Study Completion Date

904721-S01

FRT0061-0001 Rev 2
Page 1 of 1

NELSON LABORATORIES

Sponsor:
Slinda Ma
Sino Protection Medical Products Co., Lt
Area B New Station Industrial Park
Hefei, Anhui, 230051
CHINA

Viral Penetration ASTM Method F 1671 Final Report

Test Article: SPI-15-008
Purchase Order: Sino-2017001
Study Number: 997514-S01
Study Received Date: 19 Oct 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: STP0062 Rev 15
Deviation(s): None

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 30-80% relative humidity (RH), and then tested for viral penetration using a ΦX174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of ΦX174 bacteriophage. The viral penetration method complies with ASTM F1671; sampling was at the discretion of the sponsor. 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.

Number of Test Articles Tested: 3
Number of Test Articles Passed: 3
Test Article Side Tested: Either Side
Test Article Preparation: Cut from the Material at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
Compatibility Ratio: 1:1
Environmental Plate Results: Acceptable

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	1.6×10^8	1.3×10^8	<1[a]	None Seen	Pass
Negative Control	1.6×10^8	1.3×10^8	<1[a]	None Seen	Acceptable
Positive Control	1.6×10^8	1.3×10^8	TNTC[b]	Yes	Acceptable

[a] A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.
[b] TNTC = PFUs were too numerous to count.

ANAB ACCREDITED TESTING LABORATORY

Study Director Jennifer Jorgenson, B.S.
06 NOV 2017 Study Completion Date

997514-S01

FRT0062-0001 Rev 8
Page 1 of 1

普尔德 Sino Protection

产品技术数据表 Technical data sheet

1. Product information:

Material name: SPP+PE composites material
Material No.:SPI-15-008
Manufacturer: Sino Protection (Hefei) Medical Products Co., Ltd.
Composition:

Name	C.A.S NO.	Amount (%)
SPP Nonwoven(Yellow)	9003-07-0	47%
PE Film	9002 88 4	53%

Remarks:
The specific chemical identity of the fiber and the components of the finish and of the colorants is with held as a trade secret.

2. Application:

Used for medical and health supplies and personal hygiene care.

3. Physical properties:

Items	Test Methods	Unit	Test Results
Basis weight	EN 29073-1	Gsm	39
Resistance to liquid penetration	AATCC 127	mbar	100
Tensile strength Dry(MD)	EN 29073	N/5cm	45
Tensile strength Dry(CD)	EN 29073	N/5cm	25
Elongation at break(MD)	EN 29073	%	460
Elongation at break(CD)	EN 29073	%	380

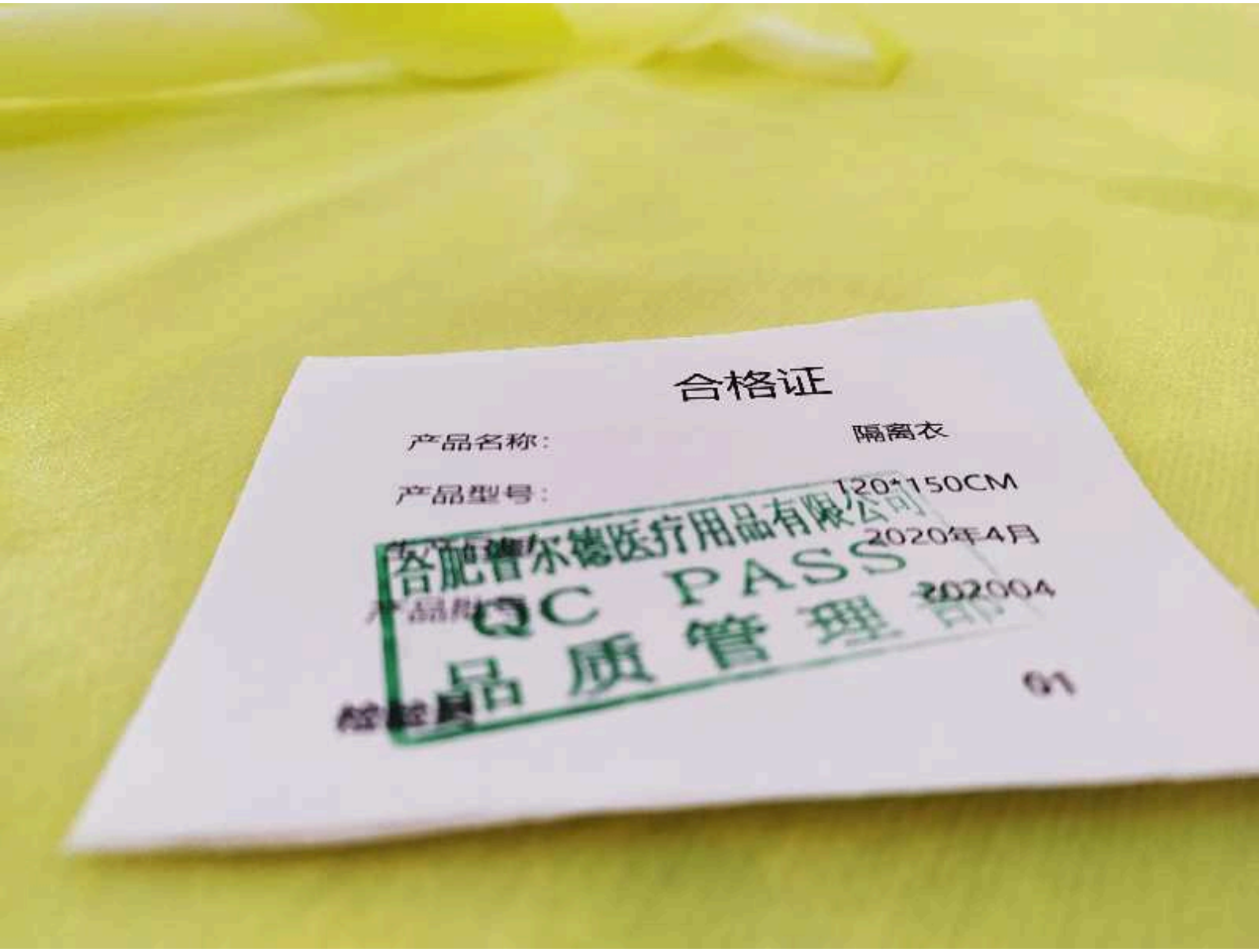
4. Application instructions:

Keep under cover in a dry and well-ventilated place, avoiding direct sunlight.

Sino Protection (HEFEI) Medical Products Co., Ltd
Address: Area B, New Station Industrial Park, Hefei City, Anhui Province, P.R. China
Tell: 86-551-64373018 Fax: 86-551-64456879 Code: 230001

普尔德
Sino Protection

Thank you


合格证
产品名称：
隔离衣
产品型号：
120*150CM
2020年4月
QC PASS
品质管理
202004
01

普尔德
Sino Protection

CATALOGUE

合肥普尔德医疗用品有限公司
Sino Protection (Hefei) Medical Products Co., Ltd


合格证
QC PASS
品质管理