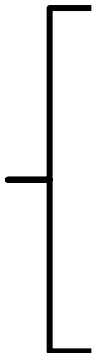


**Disposable
Isolation
Gown**



SW-0611

Contents

- **Finished Product Photo**
 - **CNAS Test Report**
 - **Material Test Report**
 - **Product Test Report**
 - **Certificates of the Company**
 - **Packing Information**
 - **Factory Photos**
 - **GMP Photos**
 - **Photo of Company**
 - **CE Claim of Conformity**
 - **FDA Listing Certificate**
- A large right-facing square bracket groups the last four items of the main list: 'Certificates of the Company', 'Packing Information', 'Factory Photos', and 'GMP Photos'. A horizontal line extends from the middle of this bracket to the left, pointing towards the sub-list.
 - **License**
 - **Medical Device**
 - **Registration Certificate**
 - **Management System Certification**
 - **Record of Foreign Trade Operations**





SUNWAY (SHENZHEN) PRODUCTS LIMITED

Finished Product Photos



CNAS Test Report

  佛山中纺联检验技术服务有限公司 CNTAC Testing Service Co.,Ltd.(Foshan)	
Testing Report	
Report No: ZFLJ2622484A	Security website: www.fcl-sz.org.cn Security code: 7573503384
Page 1 of 3	

Applicant Information

Applicant Name : SUNWAY (SHENZHEN) PRODUCTS LIMITED
 Applicant Address : /
 Manufacturer : SUNWAY (SHENZHEN) PRODUCTS LIMITED

Sample Information

Sample Description : Disposable Protective Clothing
 Sample Quantity : 3 pieces
 Colour : Blue
 Size specification : SW-0611-B
 Mass per unit area : 48.45g/m²

- Sample Receiving Date : 2020-05-16
 - Report Date : 2020-05-20
 - The original sample is stuck on the test paper.


Test Performed

Judgement according to:
 Refer to GB/T 38462-2020 Textiles-Nonwoven fabrics for isolation gowns Level II
 - Selected test(s) as requested by applicants. For details, refer to attached page(s).

Pronounce




The results shown in this report refer only to sample(s) tested unless otherwise stated.
 All the items are performed in the standard conditions, except the noted cases.
 Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.


Signed for and on behalf of
 CNTAC Testing Service Co.,Ltd.(Foshan)

Approved by


广东省佛山市南海区西樵镇南方技术创新中心一、二期 四楼 1, 314F., Nantang Technology Innovation Center, Hqiao/Yaohai District, Foshan, Guangdong, China
 Tel: (86) 757 86850633/86809656 Fax: 86850633 [Http://www.fcl.org.cn](http://www.fcl.org.cn)
 本报告国家认可，请于收到报告之日起 15 日内向检测机构反馈，逾期不予受理。



CNAS Test Report

   佛山中纺联检验技术服务有限公司 CNTAC Testing Service Co.,Ltd.(Foshan)			
Testing Report		Security website: www.fcl-sz.org.cn Security code: 7573503384	
Report No: ZFLJ2622484A		Page 2 of 3	
--- Test Result ---			
Test Result	Requirements	Judgement	
1. Tensile Strength <u>GB/T 24218.3-2010 strip method</u> 5cm strip test, CRE tensile test machine, testing speed 100mm/min, gauge length 200mm. Unit: <N>			
Lengthwise	42.0	Lengthwise ≥ 20	Pass
Crosswise	27.1	Crosswise ≥ 20	
2. Bursting strength <u>GB/T 7742.1-2005 Densham boarder method</u> The test area of clamp is 7.3c㎡. Unit: <kPa>			
Result	116	≥ 40	Pass
3. Mass deviation rate per unit area <u>GB/T 24218.1-2009</u> The test area of clamp is 0.250mX0.200m. Unit: <%>			
Result	0	-8~+8	Pass
4. Hydrostatic Pressure <u>GB/T 24218.16-2017</u> Distilled water temperature is 21℃. The rate of increase of water pressure is 1.0kPa/min. Testing surface: face Unit: <kPa>			
Minimum value	13.6	≥ 1.8	Pass
Remarks: 1.The Hydrostatic Pressure item is unauthorized for CMA & CNAS and have no valid in law. 2. The client requires that test and requirements according to GB/T 38462-2020 standard			




广东省佛山市南海区西樵镇南方技术创新中心一、二、四楼1, 3&4F., Nanfang Technology Innovation Center, Hqiao/Jiashai District, Foshan, Guangdong, China
 Tel: (86) 757 60850633/60809058 Fax: 60850633 Http://www.fcl.org.cn
 如对检测结果有异议, 应于收到报告之日起 15 日内向检测机构提出, 逾期不予受理。

CNAS Test Report

  佛山中纺联检验技术服务有限公司 CNTAC Testing Service Co.,Ltd.(Foshan)	
Testing Report	Security website: www.fcl-sz.org.cn Security code: 7573503384
Report No: ZFLJ2622484A	Page 3 of 3

Original Sample



----- End of Report -----

TESTING SERVICES



广东省佛山市南海区西樵镇南方技术创新中心一、二期 3A4F, Hanting Technology Innovation Center, Nigao/Jianhai District, Foshan, Guangdong, China
 Tel: (86) 757 90850623/90806658 Fax: 86850633 Http://www.fcl.org.cn
 本检测报告的有效性, 依赖于检测实验室之符合 15 日内向检测单位提供, 逾期不予受理。

Material Test Report



Test Report

Verification Website: www.gtgc.net.cn

Verification Code: ONHI-1124-34

No: 20R000116

Issue Date: 2020-05-01

Applicant: SUNWAY (SHENZHEN) PRODUCTS LIMITED

Address: 101, EAST OF 301, 401&501, BUILDING E, JUNXUAN COMPANY, NO.16 YINKUI ROAD, KUIXIN COMMUNITY, KUICHONG STREET, DAPENG NEW DISTRICT, SHENZHEN, CHINA

Information confirmed by applicant:

Disposable medical protective gowns

Quantity: ten pieces

Type: SW-0611

Standard Adopted:

EN 13795-1:2019 <Surgical clothing and drapes- Requirements and test methods. Part 1: Surgical drapes and gowns>

Date Received/Date Test Started: 2020-04-10

Conclusion:

Cleanliness-microorganism[Shell]	M
The resistance to dry microbial penetration[Shell]	M
The resistance to wet bacterial penetration[Shell]	M
Static hydrostatic resistance[Shell]	M
Breaking strength[Shell:dry state]	M
Breaking strength[Shell:wet state]	M
Lint and other particles generation in the dry state[Shell]	M
Bursting strength[Shell:dry state]	M
Bursting strength[Shell:wet state]	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "-"-No comment

Remark:

All the tested items are tested under the standard condition (except for indication).

Copies of the report are valid only re-stamped.

The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By:
Nan Ma Engineer

Nan Ma



Material Test Report



Test Report

No:20R000116

Cleanliness-microorganism(CFU/100cm²)[Shell]

(EN ISO 11737-1:2018, Membrane filtration method)

	Requirement
1# 0	≤300
2# 0	(Surgical gown: standard performance
3# 0	critical product area)
4# 0	(EN 13795-1:2019)
5# 0	

The resistance to dry microbial penetration(CFU)[Shell]

(EN ISO 22612:2005, The fourth generation of spores of bacillus subtilis ATCC 9372. The concentration of the spores:1.9×10⁸ CFU/g talcum powder, Sample:12, Vibration frequency:20800 times/min, Vibration time:30min)

	Requirement
1# 38	≤300
2# 47	(Surgical gown: standard performance
3# 29	less critical product area)
4# 45	(EN 13795-1:2019)
5# 39	
6# 46	
7# 31	
8# 37	
9# 48	
10# 57	

The resistance to wet bacterial penetration[Shell]

(EN ISO 22610:2006, Temp:24.5℃, Rh:56.0%, The distance of agar to plates brim:3mm, Carrier material:300μm polyurethane (PU))

The barrier index:	Requirement
1# 4.4	The barrier index:
2# 4.4	≥2.8
3# 4.4	(Surgical gown: standard performance
4# 4.4	critical product area)
5# 4.3	(EN 13795-1:2019)

Static hydrostatic resistance(cmh₂ O)[Shell]

(EN ISO 811:2018, Steadily increasing water pressure:10cmH₂ O/min, Temperature of the Water:20.2℃, Face down and face side tested)

	Requirement
1# 47.3	≥20
2# 58.1	(Surgical gown: standard performance
3# 52.3	critical product area)
4# 50.6	(EN 13795-1:2019)
5# 49.2	



Material Test Report



Test Report

No:20R000116

Breaking strength(N) [Shell: dry state]

(EN 29073-3:1992, Dry state, The distance between the clamps:200mm, Rate:100mm/min)
(EN 29073-3:1992 eqv ISO 9073-3:1989)

Length:
1# 124.8
2# 122.8
3# 127.1
4# 126.1
5# 125.0
Width:
1# 60.8
2# 66.1
3# 65.0
4# 60.8
5# 64.1

Requirement
Length ≥ 20

Width ≥ 20
(Surgical gown: standard performance
critical product area)
(EN 13795-1:2019)

Breaking strength(N) [Shell: wet state]

(EN 29073-3:1992, Wet state, The distance between the clamps:200mm, Rate:100mm/min)
(EN 29073-3:1992 eqv ISO 9073-3:1989)

Length:
1# 129.2
2# 125.8
3# 118.7
4# 121.9
5# 118.5
Width:
1# 59.9
2# 65.8
3# 67.1
4# 62.1
5# 65.7

Requirement
Length ≥ 20

Width ≥ 20
(Surgical gown: standard performance
critical product area)
(EN 13795-1:2019)

Lint and other particles generation in the dry state [Shell]

(EN ISO 9073-10:2004, Size of particles counted: $3\mu\text{m} \sim 25\mu\text{m}$)
(EN ISO 9073-10:2004 idt ISO 9073-10:2003)

Coefficient of linting:

A: Face
1# 2.2
2# 2.3
3# 2.3
4# 2.1
5# 2.2
B: FACE
1# 2.3
2# 2.2
3# 2.2
4# 2.3
5# 2.3

Requirement
Coefficient of linting:
 ≤ 4.0
(Surgical gown: standard performance
critical product area)
(EN 13795-1:2019)



Material Test Report



Test Report

No:20R000116

Bursting strength(kPa) [Shell: dry state]

(EN ISO 13938-1:1999, Dry state, Test area: 10cm²)

1# 184
2# 184
3# 172
4# 193
5# 176

Requirement

≥40

(Surgical gown: standard performance
critical product area)
(EN 13795-1:2019)

Bursting strength(kPa) [Shell: wet state]

(EN ISO 13938-1:1999, Wet state, Test area: 10cm²)

1# 164
1# 175
1# 168
1# 178
1# 181

Requirement

≥40

(Surgical gown: standard performance
critical product area)
(EN 13795-1:2019)



Product Test Report

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Total Quality. Assured.

TEST REPORT

Number:

Applicant:

Date: Apr 30, 2020

Sample Description:	
The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
Sample Name	: Non-Sterile Surgical gowns
Size(s) Range	: -
Styles/Models No.	: -
Classifications Claimed	: Standard performance
Color	: Blue
End Uses	: Non-Sterile Surgical gowns
Standard	: EN 13795-1:2019
Brand	:
Manufacturer	:
Date received/ Test Started	: April 13, 2020
Date Final Information Confirmed	: -

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch



Lin Lin
General Manager

Can / pennytao



Page 1 Of 9

Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch
3/F, Hengyun Building, 235 Kaifa Ave., Guangzhou
Economic & Technological Development District, Guangzhou, China
深圳天祥质量技术服务有限公司广州开发区分公司
中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼
Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730
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Product Test Report

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TEST REPORT

Number:

Original Sample Photo



Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch



Lin Lin
General Manager

Can / pennytao



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3/F, Hengyun Building, 235 Kaifu Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

深圳天祥质量技术服务有限公司广州开发区分公司

中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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TEST REPORT

Number:

Conclusion:

The Resistance To Dry Microbial Penetration (CFU)	M
The Resistance To Wet Bacterial Penetration	M
Cleanliness Microbial / Bioburden	M
Lint And Other Particles Generation In The Dry State	M
Hydrostatic Head Test As Received	M
Bursting Strength(kPa)	M
Tensile Strength As Received	M

Note: M = Meet Standard's Requirement
= No Comment

F = Below Standard's Requirement
N/A = Not Applicable

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch



Lin Lin
General Manager

Can / pennytao



Page 3 Of 9

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3/F, Hengyun Building, 235 Kaifu Ave., Guangzhou
Economic & Technological Development District, Guangzhou, China
深圳天祥质量技术服务有限公司广州开发区分公司
中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼
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TEST REPORT

Tests Conducted (As Requested By The Applicant)

Number:

- 1 The Resistance To Dry Microbial Penetration (CFU):
(EN ISO 22612:2005, The Fourth Generation Of Spores Of Bacillus Subtilis ATCC 9372, The Concentration Of The Spores: 1.6×10^8 CFU/G Talcum Powder, Sample:12, Vibration Frequency:20800 Times/Min, Vibration Time: 30 Min)

		Requirement
1#	7	≤ 300
2#	3	(Surgical Gown:
3#	10	Standard Performance
4#	18	Less Critical
5#	2	Product Area)
6#	3	(EN 13795-1:2019)
7#	5	
8#	12	
9#	1	
10#	3	

Remark : Test was conducted by external provider.

- 2 The Resistance To Wet Bacterial Penetration:
(EN ISO 22610:2006, Temp:24.5℃, RH:56.0 %, The Distance Of Agar To Plates Brim:3 mm, Carrier Material:30 μm Polyurethane (PU))

The Barrier Index:		Requirement
1#	6.0	The Barrier Index ≥ 2.8
2#	6.0	(Surgical Gown:
3#	6.0	Standard Performance
4#	6.0	Critical Product Area)
5#	6.0	(EN 13795-1:2019)

Remark : Test was conducted by external provider.

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Page 4 Of 9

Product Test Report

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TEST REPORT

Tests Conducted (As Requested By The Applicant)

Number:

3 Cleanliness Microbial / Bioburden

As Per BS EN 13795-1:2019 Surgical Clothing And Drapes – Requirements And Test Methods Part 1: Surgical Drapes And Gowns And EN ISO 11737-1:2018 Sterilization Of Health Care Products – Microbiological Methods – Part 1: Determination Of A Population Of Microorganisms On Products.

Test Item	Result (CFU/100cm ²)					Limit
	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	(CFU/100cm ²)
Cleanliness microbial / Bioburden	68	16	44	68	40	≤300

CFU = Colony Forming Unit

≤ = Not more than

Sample Received Condition: Sample In Unopened Original Package.

Tested Component(s) :

(1) Blue Surgical Gowns

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3/F, Hengyun Building, 235 Kaifa Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

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中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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TEST REPORT

Tests Conducted (As Requested By The Applicant)

Number:

- 4 Lint And Other Particles Generation In The Dry State:
(EN ISO 9073-10:2004, Size Of Particles Counted: $3\mu\text{m}\sim 25\mu\text{m}$)
(EN ISO 9073-10:2004 Idt ISO 9073-10:2003)

Coefficient Of Linting:

A: Face

1#	2.0
2#	2.1
3#	2.1
4#	2.1
5#	2.0

B: Face

1#	2.3
2#	2.2
3#	2.2
4#	2.2
5#	2.2

Requirement
Coefficient Of Linting
 ≤ 4.0
(Surgical Gown:
Standard Performance
Critical Product Area)
(EN 13795-1:2019)

Remark : Test was conducted by external provider.

- 5 Hydrostatic Head Test As Received (EN ISO 811:2018, Pressure Gradient At 10 cm/min Water Pressure):

Specimen 1	Over 20 cm H ₂ O
Specimen 2	Over 20 cm H ₂ O
Specimen 3	Over 20 cm H ₂ O
Specimen 4	Over 20 cm H ₂ O
Specimen 5	Over 20 cm H ₂ O
Median (M _d)	Over 20 cm H ₂ O
Lower Quartile Value (L _d)	Over 20 cm H ₂ O

Requirement
 ≥ 20 cm H₂O

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Product Test Report

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TEST REPORT

Tests Conducted (As Requested By The Applicant)

Number:

6 Bursting Strength(kPa):

Dry State

(EN ISO 13938-1:1999, Dry state, Test Area: 10 cm²)

1#	102
2#	130
3#	121
4#	117
5#	124

Requirement

≥40 kPa
(Surgical Gown:
Standard Performance
Critical Product Area)
(EN 13795-1:2019)

Wet State

(EN ISO 13938-1:1999, Wet state, Test Area: 10 cm²)

1#	122
2#	130
3#	136
4#	124
5#	128

≥40 kPa
(Surgical Gown:
Standard Performance
Critical Product Area)
(EN 13795-1:2019)

Remark : Test was conducted by external provider.

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Product Test Report

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TEST REPORT

Tests Conducted (As Requested By The Applicant)

Number:

7 Tensile Strength As Received (EN 29073-3:1992, 5-cm Cut Strip Test, Tensile Testing Machine, CRE):

				Requirement
	<u>Sleeve</u>	<u>Dry Back Panel</u>	<u>Front Panel</u>	
<u>Length Direction</u>				
Specimen 1	51.0 N	113.1 N	104.1 N	
Specimen 2	46.4 N	108.6 N	109.9 N	
Specimen 3	48.9 N	100.6 N	109.0 N	
Specimen 4	50.9 N	105.6 N	114.5 N	
Specimen 5	48.0 N	109.4 N	111.0 N	
Median (M _d)	48.9 N	108.6 N	109.9 N	
Lower Quartile Value (L _q)	48.0 N	105.6 N	109.0 N	≥ 20 N
<u>Width Direction</u>				
Specimen 1	103.1 N	59.0 N	57.3 N	
Specimen 2	101.1 N	60.8 N	56.9 N	
Specimen 3	100.4 N	56.2 N	61.0 N	
Specimen 4	97.5 N	58.7 N	54.6 N	
Specimen 5	99.8 N	61.8 N	58.8 N	
Median (M _d)	100.4 N	59.0 N	57.3 N	
Lower Quartile Value (L _q)	99.8 N	58.7 N	56.9 N	≥ 20 N

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Product Test Report

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TEST REPORT

Tests Conducted (As Requested By The Applicant)

Number:

		Requirement	
		Wet	
	Sleeve	Back Panel	Front Panel
<u>Length Direction</u>			
Specimen 1	54.2 N	120.4 N	118.0 N
Specimen 2	57.5 N	119.4 N	124.0 N
Specimen 3	52.8 N	124.5 N	115.4 N
Specimen 4	61.5 N	125.0 N	114.9 N
Specimen 5	55.2 N	113.4 N	116.6 N
Median (M _d)	55.2 N	120.4 N	116.6 N
Lower Quartile Value (L _q)	54.2 N	119.4 N	115.4 N
			≥ 20 N
<u>Width Direction</u>			
Specimen 1	111.9 N	56.9 N	59.5 N
Specimen 2	104.0 N	54.8 N	54.2 N
Specimen 3	108.0 N	55.5 N	48.0 N
Specimen 4	111.9 N	59.7 N	55.8 N
Specimen 5	105.9 N	59.9 N	55.4 N
Median (M _d)	108.0 N	56.9 N	55.4 N
Lower Quartile Value (L _q)	105.9 N	55.5 N	54.2 N
			≥ 20 N

Remark : N = Newton

End of Report

This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in these terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct. No copy of the test report (except for full text copy) shall be made without the written approval by Intertek.

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3/F, Hengyun Building, 235 Kaifa Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

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中国广州经济技术开发区开发大道 235 号恒运大厦 3 楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

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Certificates of the Company



统一社会信用代码
91440300799201478B

营 业 执 照
(副 本)



名 称 深圳市山而威户外装备科技有限公司

类 型 有限责任公司

法定代表人 李光曦

成 立 日 期 2007年04月02日

住 所 深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司B栋厂房101、301东、401、501

重 要 提 示

1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息，请登录左下角的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内，向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登 记 机 关 

2019 年 09 月 05 日

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>

国家市场监督管理总局监制

Certificates of the Company



第二类医疗器械经营备案凭证

备案编号：粤深食药监械经营备 202033323 号

企业名称	深圳市山而威户外装备科技有限公司
法定代表人	李光曦
企业负责人	李光曦
经营方式	批零兼营
住 所	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
经营场所	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
库房地址	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
经营范围	<p>2002 年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外</p> <p>2017 年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外</p>

备案部门（公章）

备案日期：2020 年 03 月 11 日





SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company

医疗器械网络销售信息公示

关闭

企业信息

企业名称	深圳市山而威户外装备科技有限公司	社会信用代码	91440300799201478B
法定代表人	李光耀	企业负责人	李光耀
住所	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501	经营场所或生产场所	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501
库房地址	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501	备案编号	粤深械网备202003110316
医疗器械生产(经营)许可证或备案凭证编号	粤深食药监械经营备202033323号	主体业态(可多选)	<input type="checkbox"/> 医疗器械生产 <input type="checkbox"/> 医疗器械批发 <input type="checkbox"/> 医疗器械零售 <input checked="" type="checkbox"/> 医疗器械批零兼营
*经营范围	2002年分类目录(二类): 6801, 6802, 6803, 6804, 6805, 6806, 6807, 6808, 6809, 6810, 6812, 6813, 6815, 6816, 6820, 6821, 6822, 6823, 6824, 6825, 6826, 6827, 6828, 6830, 6831, 6832, 6833, 6834, 6840 (诊断试剂不需低温冷藏运输贮存); 6841, 6845, 6846, 6854, 6855, 6856, 6857, 6858, 6863, 6864, 6865, 6866, 6870, 6877, 以上类别中包含的植入和介入类产品除外, 以上类别中包含的角膜接触镜、助听器产品除外[br]2017年分类目录(二类): 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 以上类别中包含的植入和介入类产品除外, 以上类别中包含的角膜接触镜、助听器产品除外		
联系人姓名	李光耀	联系人电话	13695180593


销售类型

医疗器械网络销售类型	<input type="checkbox"/> 自建类 <input checked="" type="checkbox"/> 入驻类	申请日期:	2020-03-11
网站名称	网络客户端应用程序名		
网站域名	网站IP地址		
电信业务经营许可证编号	非经营性互联网信息服务备案编号		
服务器存放地址	互联网药品信息服务资格证书编号(自建类必填)		
医疗器械网络交易服务第三方平台名称	浙江天猫网络有限公司 浙江淘宝网络有限公司 杭州阿里巴巴广告有限公司 叮当快药科技集团有限公司 深圳市腾讯计算机系统有限公司	医疗器械网络交易服务第三方平台备案凭证编号	(浙) 网械平台备字【2018】第00002号 (浙) 网械平台备字【2018】第00004号 (浙) 网械平台备字【2018】第00001号 (京) 网械平台备字【2018】第00006号 (粤) 网械平台备字【2019】第00003号

变更信息

Certificates of the Company

INGEER CERTIFICATION ASSESSMENT SERVICES



管理体系认证证书


认证编号: 117 20 QU 0122-01 R0M

兹证明 **深圳市山而威户外装备科技有限公司**
统一社会信用代码 **91440300799201478B**

注册地址 **广东省深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501**
审核地址 **广东省深圳市大鹏新区葵涌街道银葵路 16 号君轩公司 E 栋厂房 101、201、301 东、401、501**


经现场评审满足: GB/T19001-2016/ISO9001:2015 质量管理体系要求




认证范围 **帐篷的生产和销售及照明器具的生产和外销**

核准: 

初次发证: 2020 年 01 月 13 日
有效期至: 2023 年 01 月 12 日

上海英格尔认证有限公司
国家认监委批准号: CNCA-R-2003-117
电话: 400-182-9001/+86 21-51114700
网址: www.icas.org.cn
地址: 上海市徐汇区中山西路2368号
华康大厦801室 200235


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第一次监督	第二次监督	第三次监督

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Certificates of the Company

INGER CERTIFICATION ASSESSMENT SERVICES



MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 20 GU 0122-01 R0M
This is to certify the quality management systems of

Sunway (Shenzhen) Products Limited

Unified Social Credit Code 91440300799201478B

Registered Address 101, East of 301, 401, 501, E Building, Junxuan Company,
16# Yinkui Road, Kaixin Community, Kuichong Street,
Dapeng New District, Shenzhen, Guangdong, China

Auditing Address 101, 201, East of 301, 401, 501, E Building, Junxuan
Company, 16# Yinkui Road, Kuichong Street, Dapeng
New District, Shenzhen, Guangdong, China

has been assessed and registered as meeting the requirements of
GB/T19001-2016/ISO9001:2015
Scope of approval
Production and Sales of Tents, Production and Export of Lighting Fixtures

Signed by: 

First Certification: 13 Jan. 2020
Expiry Date: 12 Jan. 2023

Shanghai Ingeer Certification Assessment Co., Ltd.
Certification and Accreditation Administration of PRC (CNCA) 2005.111
Tel: 400-162-3001/96 21-51154700
Web: www.ican.org.cn
Add: Room 901, Building Minshun, 20008 West Zhongshan Rd,
Auhai District, Shanghai, China 200028



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SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company

对外贸易经营者备案登记表

备案登记表编号: 02520799

统一社会信用代码: 91440300799201478B

进出口企业代码: _____

经营者中文名称	深圳市山而威户外装备科技有限公司		
经营者英文名称	SUNWAY(SHENZHEN) PRODUCTS LIMITED		
组织机构代码	-----	经营者类型 (由备案登记机关填写)	私营有限责任公司
住 所	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501		
经营场所 (中文)	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501		
经营场所 (英文)	101, east of 301, 401&501, Building E, Junxuan company, NO.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen		
联系电话	0755-29450963	联系传真	0755-29451163
邮政编码	518104	电子邮箱	13392872595@163.com
工商登记注册日期	2007-4-2	工商登记注册号	_____

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	李光曦	有效证件号	430219197112261639
注册资金	伍佰万元	(折美元)	

依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容

企业法定代表人/ 个体工商户负责人姓名	_____	有效证件号	_____
企业资产/个人财产	_____	(折美元)	

备注	_____
----	-------

填表前请认真阅读背面的条款,并由企业法定代表人或个体工商户负责人签字、盖章。

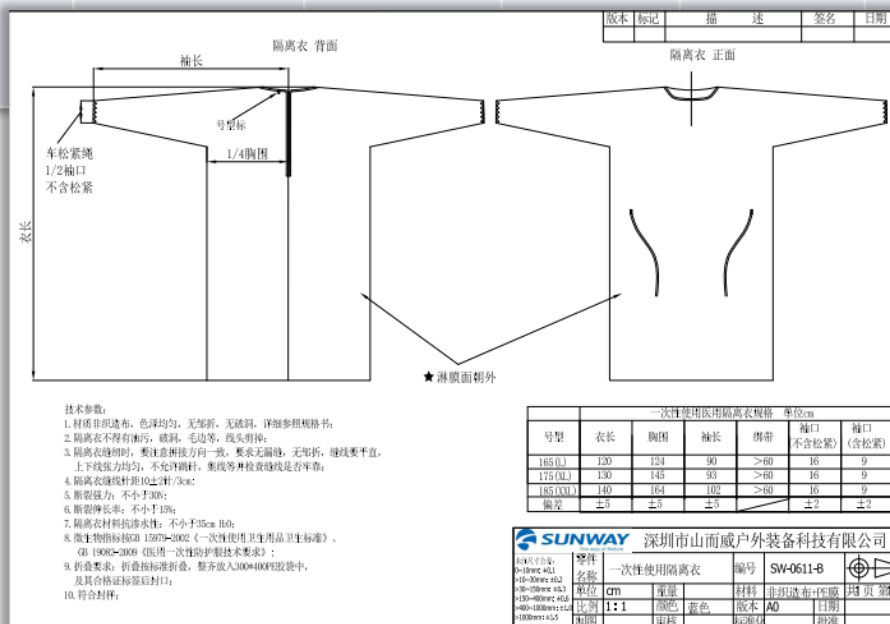


2019

年 月 日

Packaging Information

No.	Unit Package	Qty (Pcs) /Carton	Measurement			N.W. (KGS)	G.W. (KGS)
			Length (cm)	Width (cm)	Height (cm)		
1	1pcs/bag	100pcs	43	43	36	12.50	13.50





SUNWAY (SHENZHEN) PRODUCTS LIMITED

Factory Photos






SUNWAY (SHENZHEN) PRODUCTS LIMITED

Photo of the Company



CE Claim of Conformity

 **CIBG**
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Datum: 6 mei 2020
Betreft: aanmelding medische hulpmiddelen klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 17 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf SUNWAY (SHENZHEN) PRODUCTS LIMITED met Europees gemachtigde SUNGO Europe B.V. onderstaande medische hulpmiddelen, ingedeeld in risicoklasse I, aflevert. De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende een of meer van deze producten het bijbehorende kenmerk te vermelden.

Disposable Medical Face Mask
(geen merknaam) (NL-CA002-2020-50600)
Disposable Medical Goggles
(geen merknaam) (NL-CA002-2020-50599)
Disposable Medical Protective Gowns
(geen merknaam) (NL-CA002-2020-50598)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling - verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiestelsel.

Farmatec
Bezoekadres:
Hofforen
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:
J.I. van de Leuv
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20201509

Bijlagen
-

Uw aanvraag
17 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Pagina 1 van 2

CE Claim of Conformity

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van de bovengenoemde producten slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van de desbetreffende producten als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

A handwritten signature in blue ink, appearing to read 'M.J. van de Velde', written over a light blue circular stamp.

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

FDA



Certification of FDA Registration Service

This document provides notification of the registration number assigned to the client's establishment.

Establishment: SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address: E Building, Jinxuan company, 16# Yankui Road, Kuixin community, Kuichong street, Dapeng New District, Shenzhen, Guangdong, 518119, CHINA

Owner/Operator No.: 10064363
Registration No.: 3014331592

Listing No.	Premarket Submission No.	Product Codes	Device Name	Activities
D378991	Exempt	MSH	Respirator, surgical	Manufacturer
D378898	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer
D403677	Exempt	FXD	SUIT, SURGICAL	Manufacturer
D403676	Exempt	DEA	Non-surgical isolation gown	Manufacturer
D403678	Exempt	KHA	MASK, SCAVENGING	Manufacturer
D403673	Exempt	FYF	CAP, SURGICAL	Manufacturer

FDA

D403675	Exempt	EYE	DRESS, SURGICAL	Manufacturer
D403674	Exempt	FACE	GOWN, SHOE, OPERATING-ROOM	Manufacturer

Field Fu
Mr. Field Fu
SHENZHEN JOYANTECH CONSULTING CO., LTD
www.cefila.com

Certification No.: FDA 202003-005 Validity: March 25, 2020 - Dec. 31st, 2020



SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

Business Trade

Name : *sunway*
(shenzhen)

Establishment

Registration or FEI

Number : 3014331592

[New Search](#)⁶

Establishment Name 7 8	Registration Number	Current Registration Yr
SUNWAY (SHENZHEN) PRODUCTS LIMITED ⁹ CHINA	3014331592	2020
<ul style="list-style-type: none">accessory, surgical apparel - Accessory,Surgical Apparel; SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Protective Gowns, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Protective Clothing, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Medical Disposable Goggles¹⁰		Manufacturer
<ul style="list-style-type: none">respirator, surgical - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Face Mask¹¹		Manufacturer
<ul style="list-style-type: none">cap, surgical - Cap,Surgical¹²		Manufacturer
<ul style="list-style-type: none">cover, shoe, operating-room - Cover,Shoe,Operating-Room¹³		Manufacturer
<ul style="list-style-type: none">dress, surgical - Dress,Surgical¹⁴		Manufacturer
<ul style="list-style-type: none">non-surgical isolation gown - Non-Surgical Isolation Gown¹⁵		Manufacturer
<ul style="list-style-type: none">suit, surgical - Suit,Surgical¹⁶		Manufacturer
<ul style="list-style-type: none">mask, scavenging - Face mask; Protective mask KN95¹⁷		Manufacturer

FDA

FDA **PRODUCT LIST**
List of products registered with the FDA

1 result found
for **Establishment**
Registration or
Business Trade
Name : sunway
(shenzhen)

[New Search](#)

Establishment Name	Registration Number	Current Registration Yr
SUNWAY (SHENZHEN) PRODUCTS LIMITED	CHINA No number listed	2020

- [Accessory, Surgical Apparel - SUN-V Blocklite/
Sunvia/ Sun Valley, Disposable Medical
Protective Gowns, Size 165/175/185/190/195;](#) Manufacturer

[SUN-V Blocklite/ Sunvia/ Sun Valley,
Disposable Protective Clothing, Size
165/175/185/190/195; SUN-V Blocklite/
Sunvia/ Sun Valley, Medical Disposable
Goggles](#)

- [Respirator, Surgical - SUN-V Blocklite/ Sunvia/
Sun Valley, Disposable Medical Face Mask](#) Manufacturer

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FDA **PRODUCT LIST**
List of products registered with the FDA

FDA

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Proprietary Name: SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Protective Gowns, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Protective Clothing, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Medical Disposable Goggles

Classification Name: ACCESSORY, SURGICAL APPAREL

Product Code: [LYU](#)

Device Class: 1

Regulation Number: [878.4040](#)

Medical Specialty: General & Plastic Surgery

Registered Establishment Name: [SUNWAY \(SHENZHEN\) PRODUCTS LIMITED](#)

Owner/Operator: [SUNWAY \(SHENZHEN\) PRODUCTS LIMITED](#)

Owner/Operator Number: 10064363

Establishment Operations: Manufacturer

Page Last Updated: 03/30/2020

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FDA

[New Search](#)[Back To Search Results](#)

Proprietary Name: SUN-V Blocklite/ Sunvia/ Sun Valley,

FDA

[SUN-V Blocklite/ Sunvia/ Sun Valley,
Disposable Protective Clothing, Size
165/175/185/190/195; SUN-V Blocklite/
Sunvia/ Sun Valley, Medical Disposable
Goggles](#)

- [Respirator, Surgical - SUN-V Blocklite/ Sunvia/
Sun Valley, Disposable Medical Face Mask](#) Manufacturer

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FDA