SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Disposable Boot/ Shoe Cover

SW-0618

Summary

- **Product Brand: Sunway Medical, Inc.**
- **Product Description: Disposable Boot/Shoe Cover**
- **Supplier Ref Number: SW-0618**
- **Product Country of Origin: China**
- **Product Name Submitted: Protective Boot/Shoe Cover (non-medical)**
- **Name of Reg. Authority: GTTC / POSI**
- **Product Standards:**
  - **Verification code: NHBR - 4064-34 / No. 200129331**
  - **POSI: ISO13485 : 2016 Cert**
  - **Cert of Analysis: COA #720021503**
- **Product Mktg Lic Number: 914403007992014 4/02/07**
- **Product Shelf Life: 2yr**
- **Prod. Intended Use: Disposable (non-medical) Boot/Shoe Cover**

Content

- Photos Of Content
- Packaging Information
- Photos Of Production Workshop
- Photo Of The Company
- Material Test Report
- Test Report
- CE Claim of Conformity
- Certificates of Company
- FDA

Photos of the Boot/Shoe Cover

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Packaging Information

No.	Unit Package	Qty（Pcs）/Carton	Measurement			N.W. (KGS)	G.W. (KGS)
			Length (cm)	Width (cm)	Height (cm)		
1	1pr/bag	500pcs	61.00	56.00	39.00	15.00	16.70

合格证

【产品名称】防护鞋套(非医用)
【规格型号】SW-0618
【主要成分】无纺布65%、PE膜 34%、 松紧带1%
【执行标准】Q/SW001-2020
【包装规格】10只/袋
【批次号】X200701Y
【生产日期】2020年7月20日
【有效期】2年
【生产商】深圳市山而威户外装备科技有限公司
【生产地址】深圳市大鹏新区葵涌街道葵新社区葵涌16号君轩公司E栋厂房101、201、301东、401、501

Quality Certificate

【Name】 Protective Shoe Cover
【Model】SW-0618
【Main Components】65%non-woven fabric、34%PE、1% Elastic Rope
【Standard】Q/SW001-2020
【Packing Spec.】10pcs/bag
【Production LOT】X200701Y
【Production Date】2020.07.20
【Validity】2 years
【Manufacturer】Sunway (Shenzhen) Products Limited
【Address】101, 201, east of 301, 401&501,Building E, junxuan Company,No.16 Yikui Road, Kuixin Community, Kuichong street,Dapeng new district, Shenzhen.

Photos of the Production Workshop

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SUNWAY (SHENZHEN) PRODUCTS LIMITED

Factory Photos

Photo of the Company

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Material Test Report

Certificate of Analysis

Document No.: QF-QA-052

Ver./Rev. No.: C/0

COA Number: 720021503

Product Code	Lot Number	Product Description	Emboss	Roll Width	Roll Length	Production Date	Test Date
LF20107	B200206023 (30054169)	77gsm White two-layer laminated material	/	1600mm	/	14-Feb-20- 15-Feb-20	14-Feb-20- 15-Feb-20

Property	UOM	sample size[2]	Lot Average	Specification[1]			Pass/Fail	Test Method
				LTGT	Target	UTGT		
Basis Weight	gsm	15	76.3	72.0	77.0	82.0	合格	ISO 9073-1
MD Strip Tensile	N	15	135.2	45.0	60.0	N/A	合格	GB/T 3923.1
CD Strip Tensile	N	15	69.9	45.0	50.0	N/A	合格	GB/T 3923.1
MD Elongation	%	15	81.2	15.0	30.0	N/A	合格	GB/T 3923.1
CD Elongation	%	15	79.4	15.0	30.0	N/A	合格	GB/T 3923.1
Hydrostatic Head Pressure	cm.H_2O	15	161.1	17.0	50.0	N/A	合格	GB/T 4744
Water Repellency	grade	15	4.0	3.0	4.0	N/A	合格	GB/T 4745
Surface Resistance	Ω	15	3.3E+09	N/A	10^{10}	10^{11}	合格	WSP 40.1
MD Electrostatic Decay	s	6	0.1	N/A	0.1	0.5	合格	WSP 40.2
CD Electrostatic Decay	s	6	0.1	N/A	0.1	0.5	合格	WSP 40.2
Roll Width	mm	3	1600	1597	1600	1603	合格	/
Appearance quality	Pass							

Inspector/Date: 15-Feb-20 **Approved by/Date:** 15-Feb-20

Note 1: Unless otherwise stated, the specification represents lot averages only.

Note 2: Sample size represents the number of specimens tested in the laboratory lot test.

Comments:

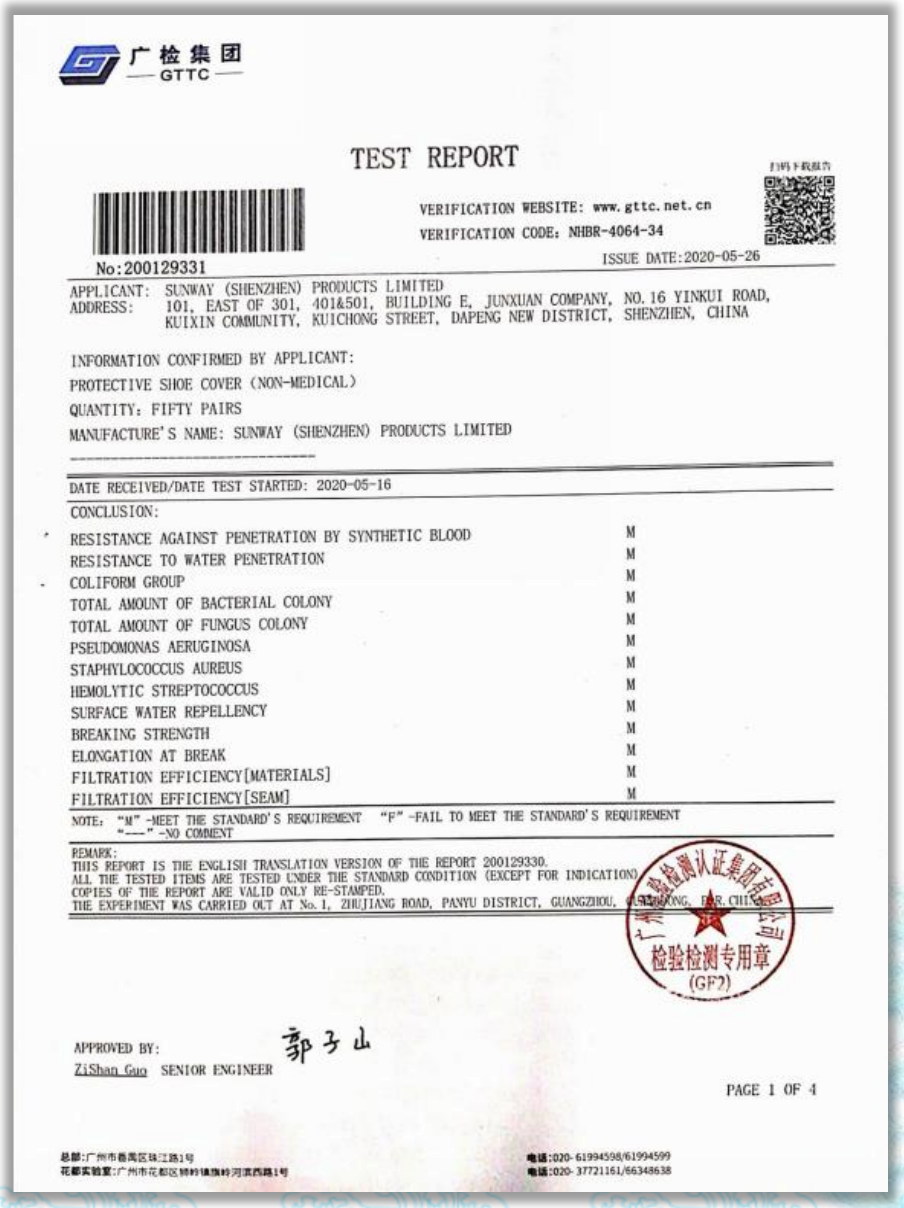
This material was approved on February 15th，2020 for shipment from

All recommendations or suggestions are made without GUARANTEE in as much as conditions and methods of commercial use are beyond our control.

Properties given are typical values for product as produced and should not be viewed as product specifications.

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Test Report



广检集团 GTTC

TEST REPORT

No:200129331

VERIFICATION WEBSITE: www.gttc.net.cn
VERIFICATION CODE: NHBR-4064-34
ISSUE DATE:2020-05-26

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:
PROTECTIVE SHOE COVER (NON-MEDICAL)
QUANTITY: FIFTY PAIRS
MANUFACTURE'S NAME: SUNWAY (SHENZHEN) PRODUCTS LIMITED

DATE RECEIVED/DATE TEST STARTED: 2020-05-16

CONCLUSION:

RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD	M
RESISTANCE TO WATER PENETRATION	M
COLIFORM GROUP	M
TOTAL AMOUNT OF BACTERIAL COLONY	M
TOTAL AMOUNT OF FUNGUS COLONY	M
PSEUDOMONAS AERUGINOSA	M
STAPHYLOCOCCUS AUREUS	M
HEMOLYTIC STREPTOCOCCUS	M
SURFACE WATER REPELLENCY	M
BREAKING STRENGTH	M
ELONGATION AT BREAK	M
FILTRATION EFFICIENCY[MATERIALS]	M
FILTRATION EFFICIENCY[SEAM]	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200129330.
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

检验检测专用章 (GF2)

APPROVED BY: 郭子山
ZiShan Guo SENIOR ENGINEER

PAGE 1 OF 4

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇狮岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

广检集团
GTTC

TEST REPORT

No:200129331

检验检测专用章
(GF2)

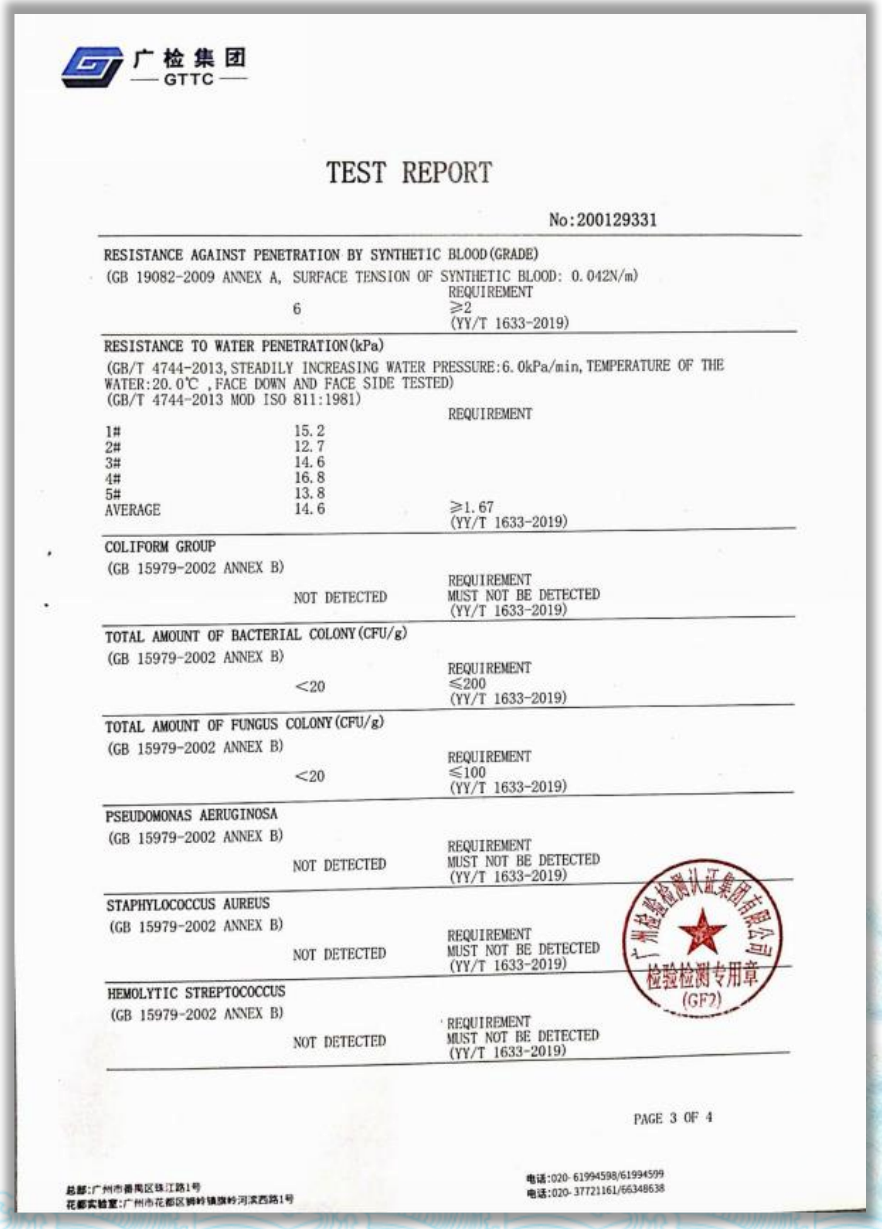
PAGE 2 OF 4

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇秋河滨西路1号

电话:020-61994598/61994599
电话:020-37721161/66348638

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Test Report



广检集团 GTTC

TEST REPORT

No:200129331

RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD(GRADE)
(GB 19082-2009 ANNEX A, SURFACE TENSION OF SYNTHETIC BLOOD: 0.042N/m)

		REQUIREMENT
	6	≥2 (YY/T 1633-2019)

RESISTANCE TO WATER PENETRATION(kPa)
(GB/T 4744-2013, STEADILY INCREASING WATER PRESSURE:6.0kPa/min, TEMPERATURE OF THE WATER:20.0℃ , FACE DOWN AND FACE SIDE TESTED)
(GB/T 4744-2013 MOD ISO 811:1981)

		REQUIREMENT
1#	15.2	
2#	12.7	
3#	14.6	
4#	16.8	
5#	13.8	
AVERAGE	14.6	≥1.67 (YY/T 1633-2019)

COLIFORM GROUP
(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY/T 1633-2019)

TOTAL AMOUNT OF BACTERIAL COLONY(CFU/g)
(GB 15979-2002 ANNEX B)

	REQUIREMENT
<20	≤200 (YY/T 1633-2019)

TOTAL AMOUNT OF FUNGUS COLONY(CFU/g)
(GB 15979-2002 ANNEX B)

	REQUIREMENT
<20	≤100 (YY/T 1633-2019)

PSEUDOMONAS AERUGINOSA
(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY/T 1633-2019)

STAPHYLOCOCCUS AUREUS
(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY/T 1633-2019)

HEMOLYTIC STREPTOCOCCUS
(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY/T 1633-2019)

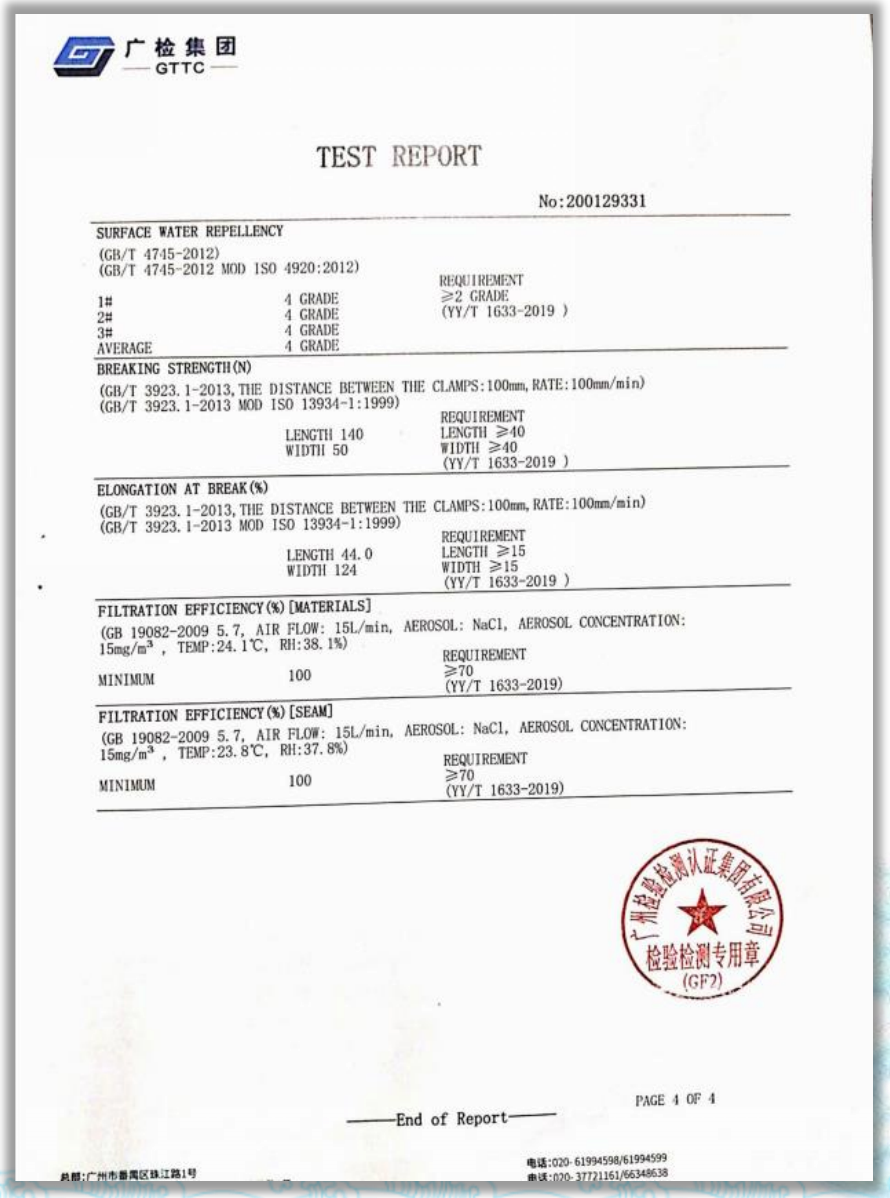
广州检验检测认证集团有限公司 检验检测专用章 (GF2)

PAGE 3 OF 4

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇狮岭河滨西路1号

电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report



广检集团 GTTC

TEST REPORT

No:200129331

SURFACE WATER REPELLENCY
(GB/T 4745-2012)
(GB/T 4745-2012 MOD ISO 4920:2012)

		REQUIREMENT
1#	4 GRADE	≥2 GRADE
2#	4 GRADE	(YY/T 1633-2019)
3#	4 GRADE	
AVERAGE	4 GRADE	

BREAKING STRENGTH(N)
(GB/T 3923.1-2013, THE DISTANCE BETWEEN THE CLAMPS:100mm, RATE:100mm/min)
(GB/T 3923.1-2013 MOD ISO 13934-1:1999)

		REQUIREMENT
	LENGTH 140	LENGTH ≥40
	WIDTH 50	WIDTH ≥40
		(YY/T 1633-2019)

ELONGATION AT BREAK(%)
(GB/T 3923.1-2013, THE DISTANCE BETWEEN THE CLAMPS:100mm, RATE:100mm/min)
(GB/T 3923.1-2013 MOD ISO 13934-1:1999)

		REQUIREMENT
	LENGTH 44.0	LENGTH ≥15
	WIDTH 124	WIDTH ≥15
		(YY/T 1633-2019)

FILTRATION EFFICIENCY(%)[MATERIALS]
(GB 19082-2009 5.7, AIR FLOW: 15L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m^3, TEMP:24.1℃, RH:38.1%)

		REQUIREMENT
MINIMUM	100	≥70
		(YY/T 1633-2019)

FILTRATION EFFICIENCY(%)[SEAM]
(GB 19082-2009 5.7, AIR FLOW: 15L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m^3, TEMP:23.8℃, RH:37.8%)

		REQUIREMENT
MINIMUM	100	≥70
		(YY/T 1633-2019)

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

End of Report

PAGE 4 OF 4

总部:广州市番禺区珠江路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

SUNWAY

认证证书 ◆ CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE

POSI

CERTIFICATE

This is to certify that the Quality Management System of

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Business license number: 91440300799201478B

Registered Address: 101, 201, East of 301, 401 &501, Building E, Junxuan Company, No.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, Guangdong Province, China

Audit Address: 101, 201, East of 301,401 &501, Building E, Junxuan Company, No.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, Guangdong Province, China

applicable to

Production and sales of disposable medical isolation clothing, medical isolation face shield, medical isolation eye mask, disposable medical coverall isolation clothing，medical isolation shoe cover(in the filing certificate)；Production and sales of daily protective face masks；Production and sales of disposable protective clothing(export only)

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

ANAB ACCREDITED ISO/IEC 17021-1 MANAGEMENT SYSTEMS CERTIFICATION BODY

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

General Manager

Certificate Registration No：381200045R0M

Initial issue date：2020.06.11 Issue date：2020.06.11 Valid until: 2023.06.10

Shanghai POSI Certification Co., Ltd.

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

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

Farmatec
Bezoekadres:
Hoftoren
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.

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.

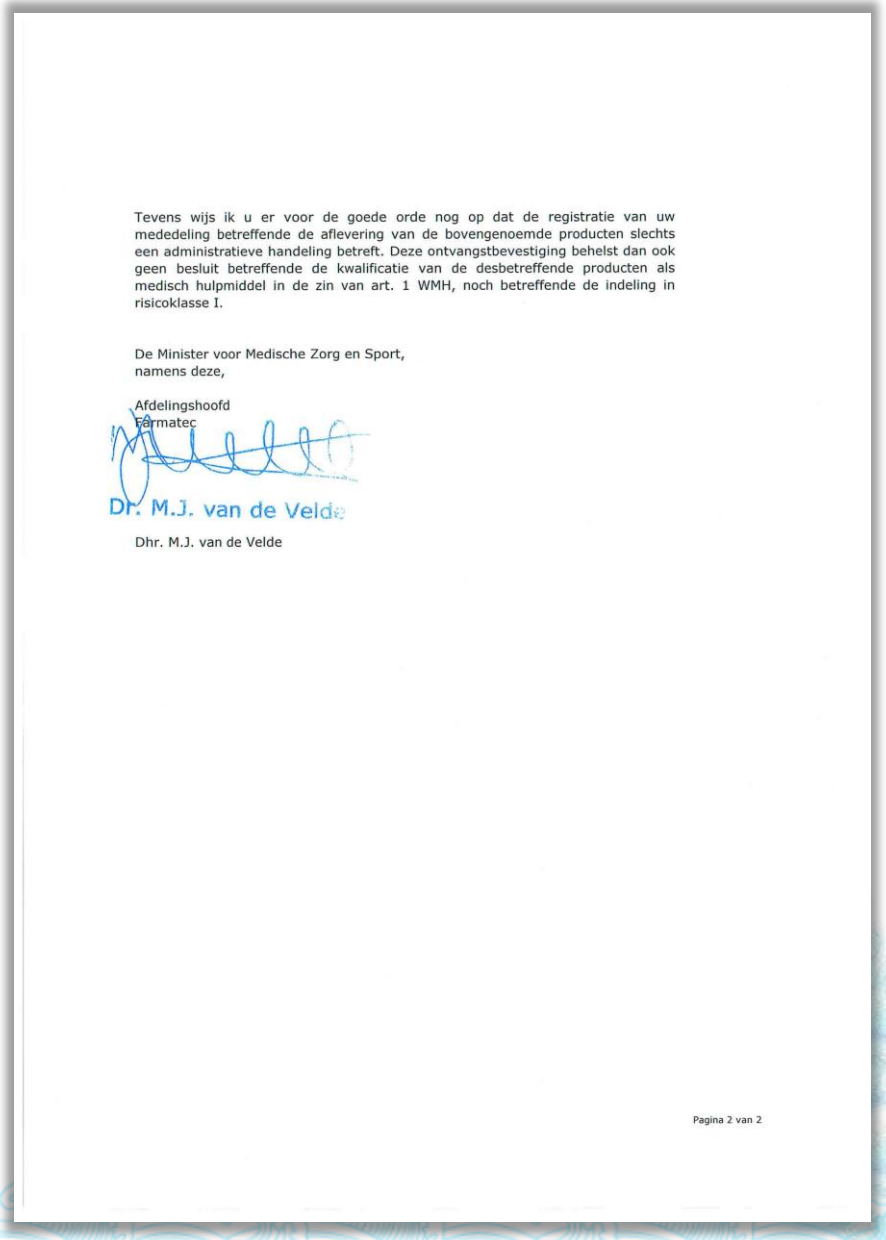
Disposable Medical Face Mask
(geen merknaam) (NL-CA002-2020-50600)
Disposable Medical Goggles
(geen merknaam) (NL-CA002-2020-50599)
Disposable Medical Protective Gowns
(geen merknaam) (NL-CA002-2020-50598)

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 vigilantiesysteem.

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,

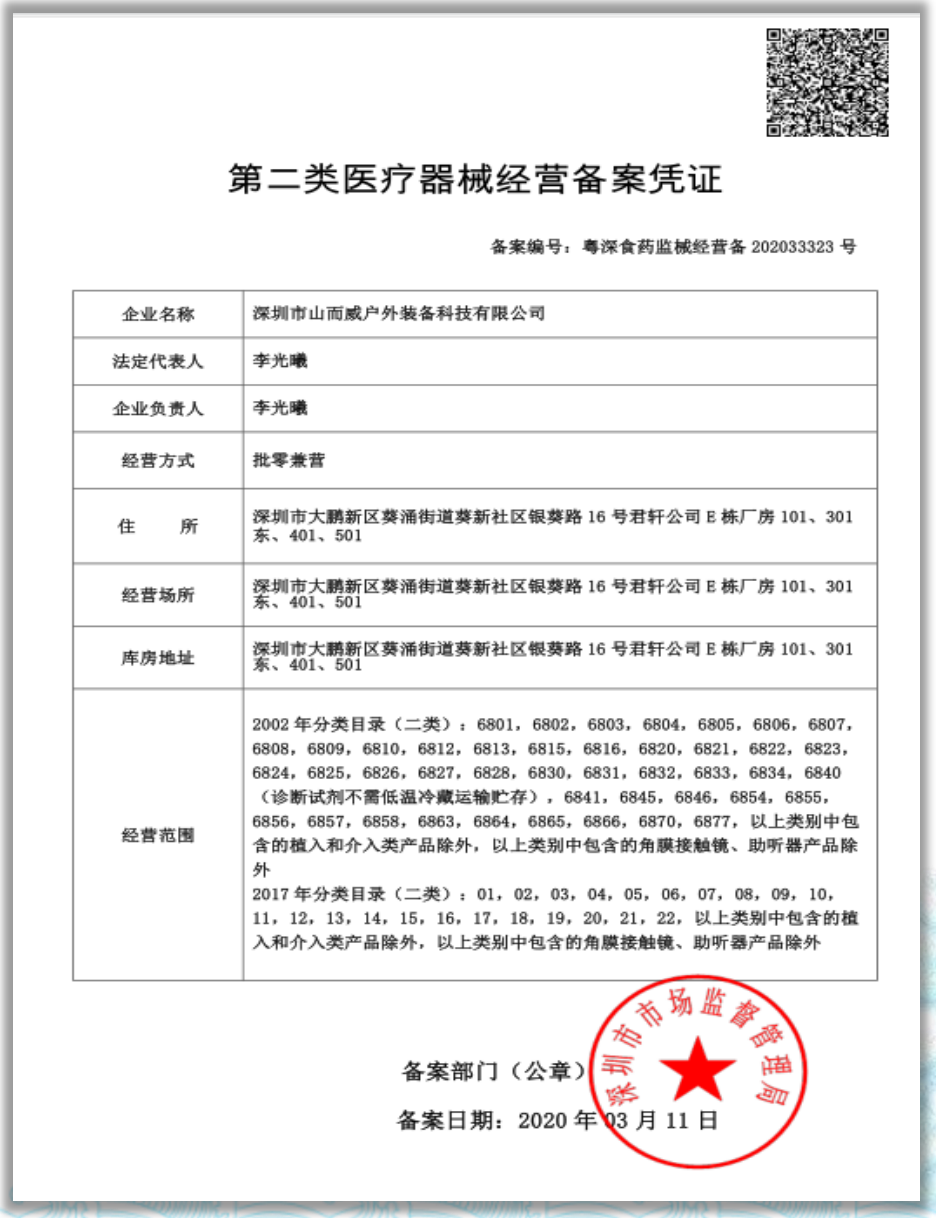
Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

Pagina 2 van 2

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	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 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

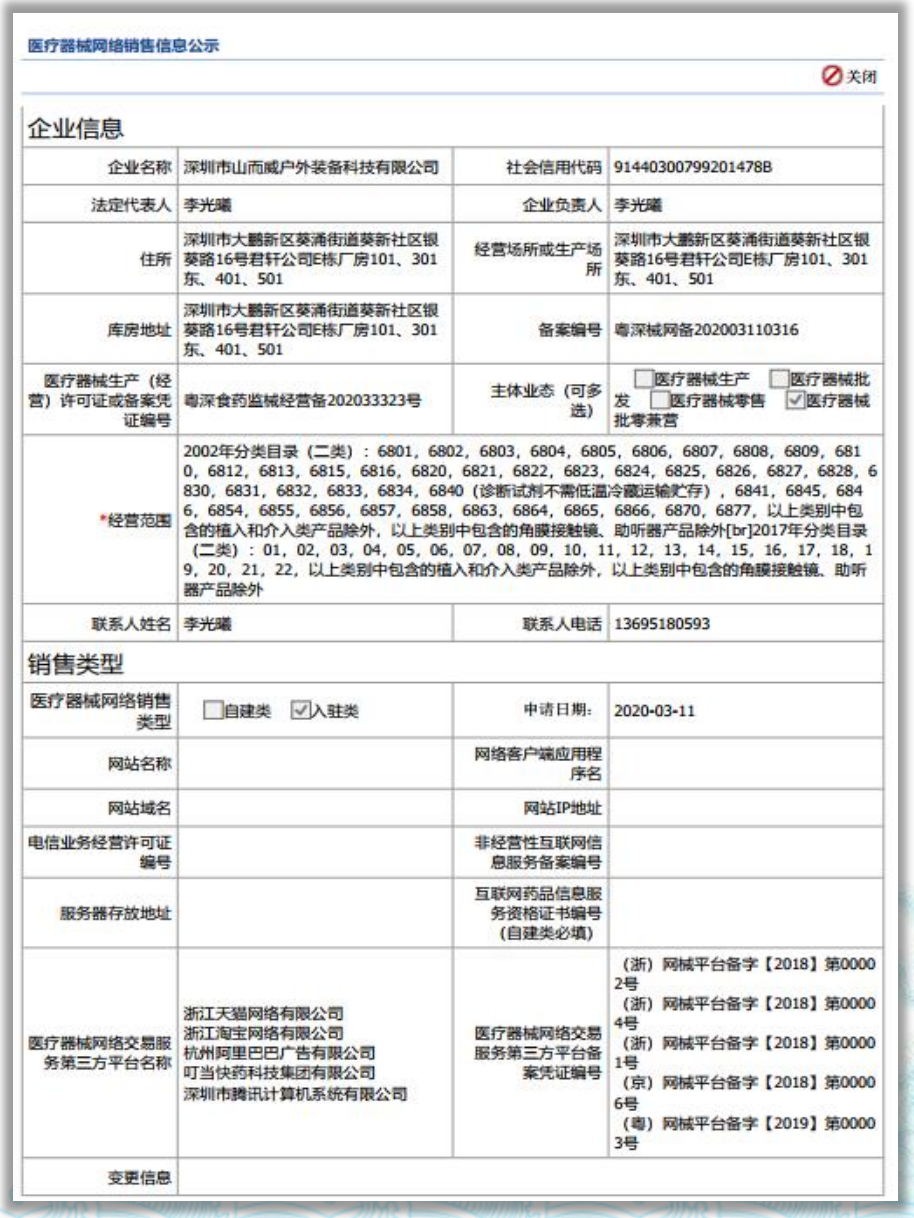
备案部门（公章）

备案日期：2020 年 03 月 11 日

SUNWAY

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	李光曙	企业负责人	李光曙
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）	☐医疗器械生产 ☐医疗器械批发 ☐医疗器械零售 ☑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	李光曙	联系人电话	13695180593

销售类型

医疗器械网络销售类型	☐自建类 ☑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

第一类医疗器械备案信息表

备案号：粤深械备 20200184 号

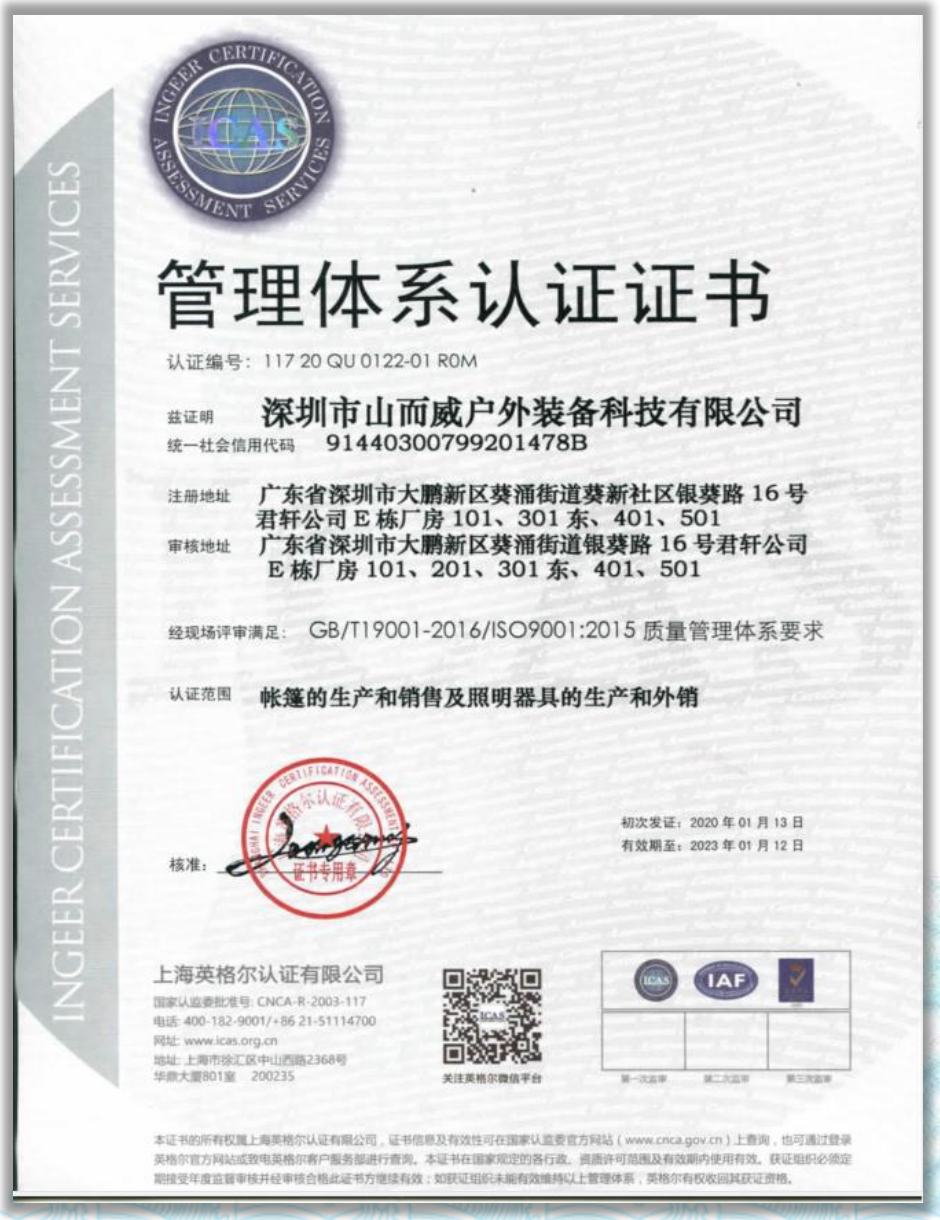
备案人名称	深圳市山而威户外装备科技有限公司
统一社会信用代码	9144030079920147 8B
备案人注册地址	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
生产地址	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
产品名称	一次性使用医用连体隔离衣
型号/规格	型号：连体衣；规格：160、165、170、175、180、185
产品描述	采用非织造布为主要原料，经裁剪、缝纫而成。非无菌提供，一次性使用。
预期用途	用于医疗机构门诊、病房、检验室作普通隔离。
备注	
备案单位和日期	深圳市市场监督管理局 备案日期：2020-03-11
变更情况	

深圳市市场监督管理局 许可（备案）业务专用章 (1-3)

深圳市场局网站，可验证本证书，
方法 1：详见市场局网站“药械信息查询栏目”：
https://amr.sz.gov.cn/szyj/zwgk/search.jsp
方法 2：访问深圳市场局网站 http://amr.sz.gov.cn
点击首页的 -政务服务 -信息查询 -药械信息查询，内有一类备案等市局证书的查询界面。
以上网页，推荐 IE11 浏览器打开，并打开兼容视图设置，添加网址 sz.gov.cn 。

SUNWAY (SHENZHEN) PRODUCTS LIMITED

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号华鼎大厦801室　200235

关注英格尔微信平台

本证书的所有权属上海英格尔认证有限公司，证书信息及有效性可在国家认监委官方网站（www.cnca.gov.cn）上查询，也可通过登录英格尔官方网站或致电英格尔客户服务部进行查询。本证书在国家规定的各行政、资质许可范围及有效期内使用有效。获证组织必须定期接受年度监督审核并经审核合格此证书方继续有效；如获证组织未能有效维持以上管理体系，英格尔有权收回其获证资格。

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company

INGEER CERTIFICATION ASSESSMENT SERVICES

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 20 QU 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, Kuixin 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.

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

成立日期　2007年04月02日

法定代表人　李光曦

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

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　深圳市市场监督管理局

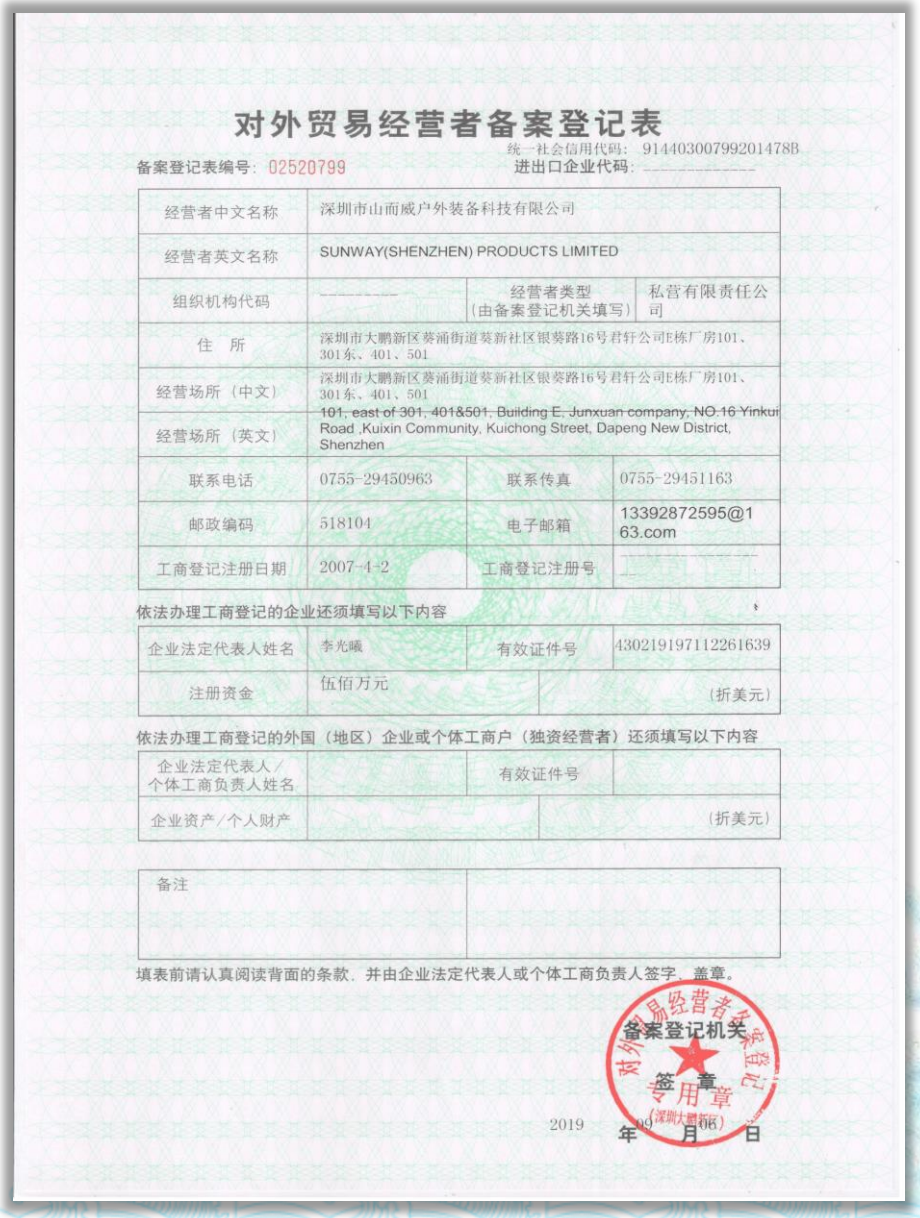
2019 年 09 月 05 日

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company



对外贸易经营者备案登记表

统一社会信用代码：914403007992014788

备案登记表编号：02520799　　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负责人签字、盖章。

备案登记机关

签　章

2019　年　09　月　06　日

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

Certification of FDA Registration Service

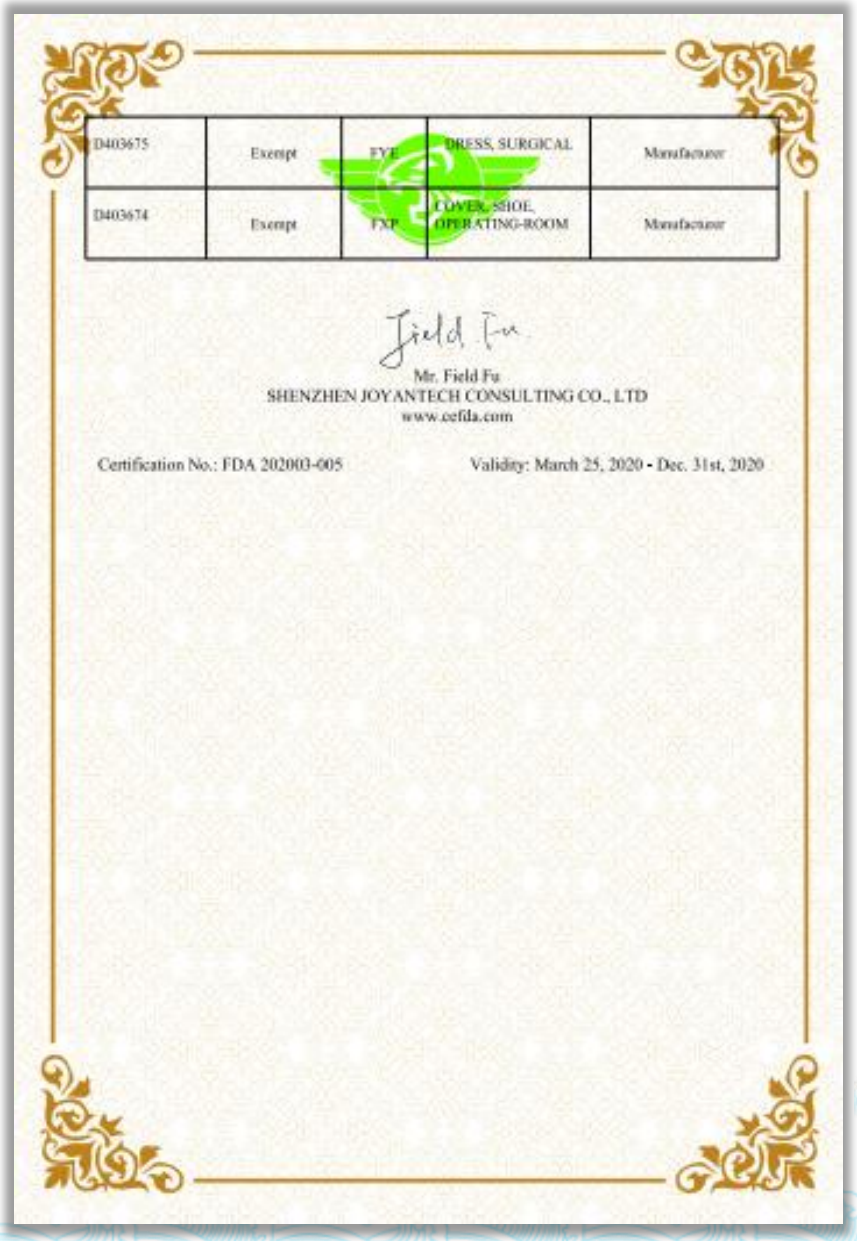
This document provides notification of the registration number assigned to the client's establishment.

Establishment: SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address: E Building,Junxuan company,16# Yinkui 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
D378901	Exempt	MSH	Respirator, surgical	Manufacturer
D378898	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer
D403677	Exempt	FXO	SUIT, SURGICAL	Manufacturer
D403676	Exempt	OEA	Non-surgical isolation gown	Manufacturer
D403678	Exempt	KHA	MASK, SCAVENGING	Manufacturer
D403673	Exempt	FYF	CAP, SURGICAL	Manufacturer

FDA



D403675	Exempt	FYE	DRESS, SURGICAL	Manufacturer
D403674	Exempt	FXP	COVER, SHOE, OPERATING-ROOM	Manufacturer

Field Fu

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

Certification No.: FDA 202003-005

Validity: March 25, 2020 - Dec. 31st, 2020

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

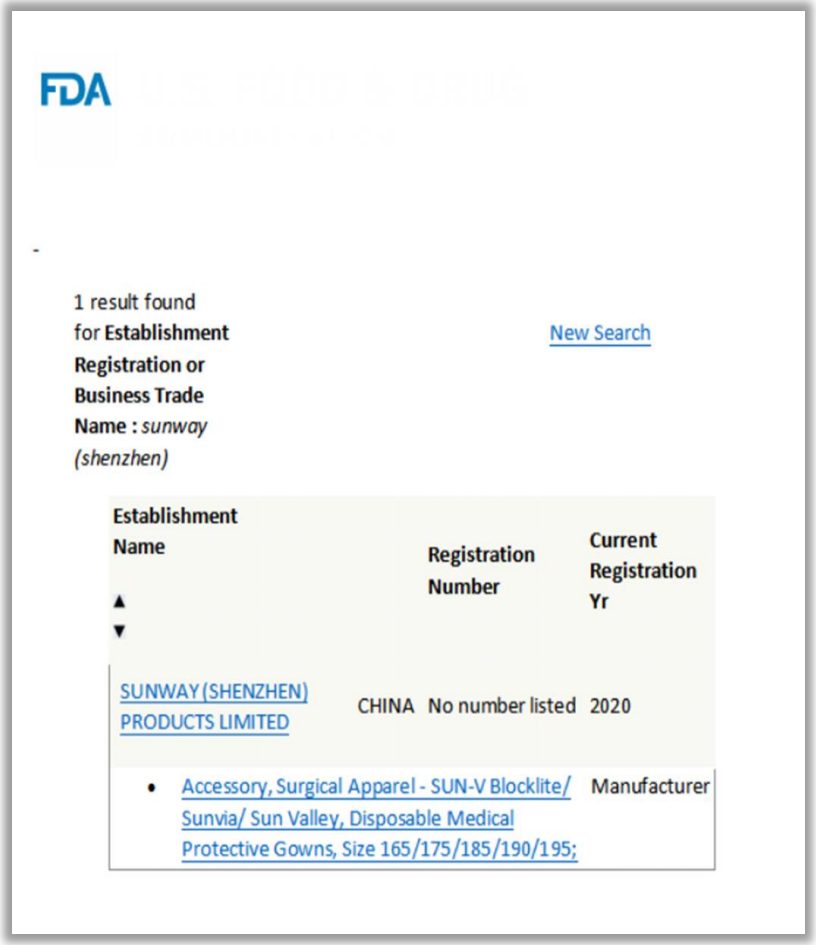
Business Trade Name : *sunway (shenzhen)*
Establishment Registration or FEI Number : *3014331592*

New Search[6]

Establishment Name [7] [8]	Registration Number	Current Registration Yr
SUNWAY (SHENZHEN) PRODUCTS LIMITED[9] CHINA	3014331592	2020
• 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 Goggles [10]		Manufacturer
• respirator, surgical - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Face Mask [11]		Manufacturer
• cap, surgical - Cap,Surgical [12]		Manufacturer
• cover, shoe, operating-room - Cover,Shoe,Operating-Room [13]		Manufacturer
• dress, surgical - Dress,Surgical [14]		Manufacturer
• non-surgical isolation gown - Non-Surgical Isolation Gown [15]		Manufacturer
• suit, surgical - Suit,Surgical [16]		Manufacturer
• mask, scavenging - Face mask; Protective mask KN95 [17]		Manufacturer

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA



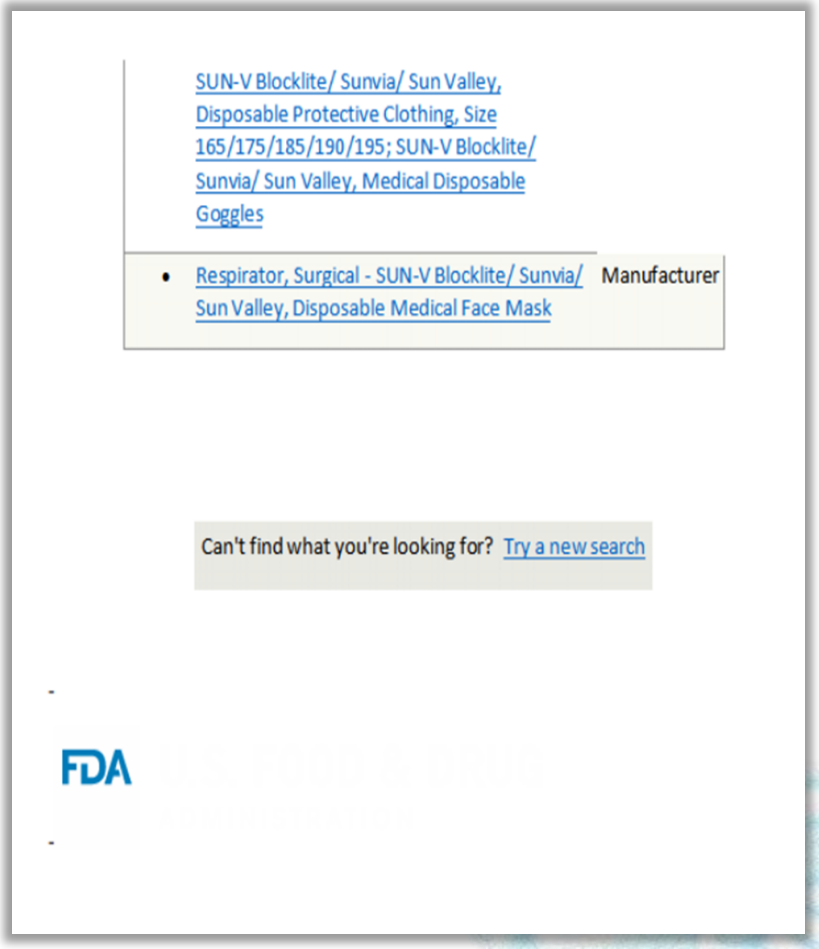
FDA

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

Can't find what you're looking for? Try a new search

FDA

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

New Search Back To Search Results

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

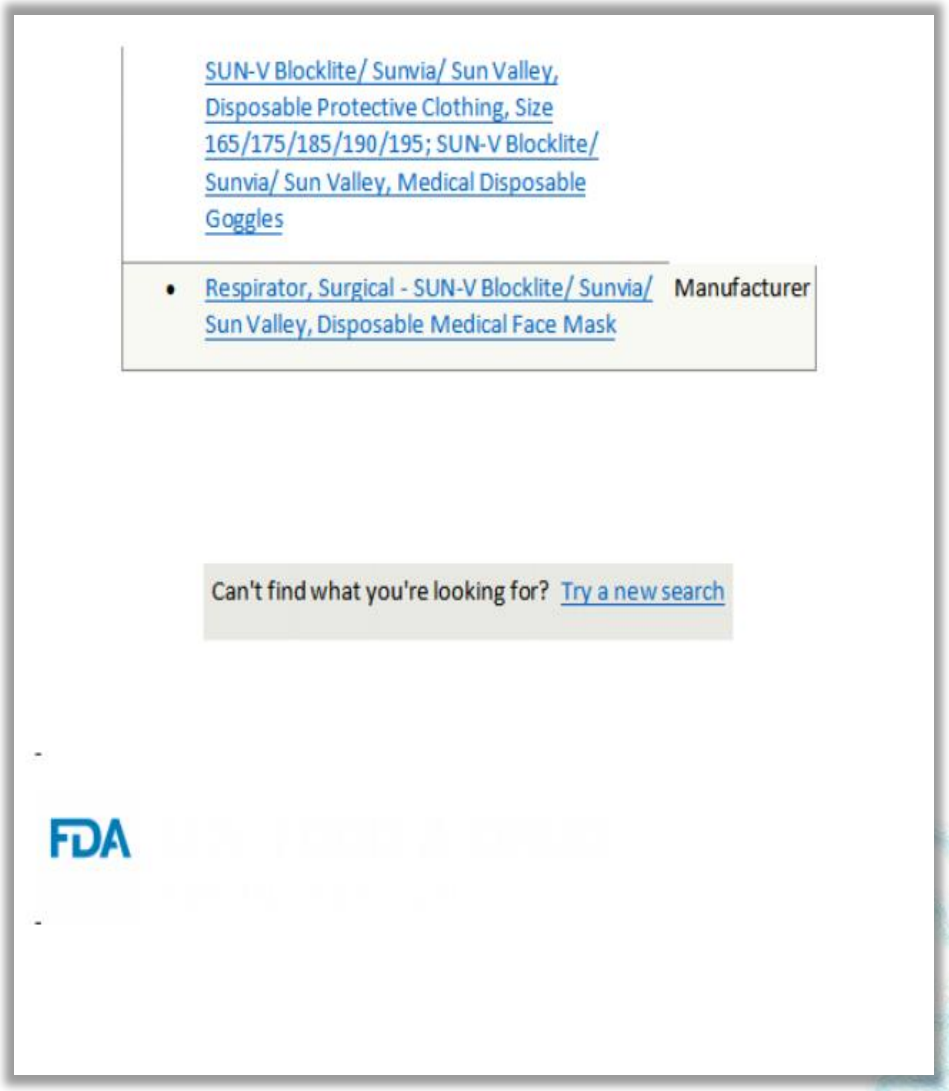
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

New Search Back To Search Results

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA