SUNWAY (SHENZHEN) PRODUCTS LIMITED

Disposable Medical Face Mask
Level 2 & Level 3

SW-0614

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Summary

- **Product Brand: Sunway Medical, Inc.**
- **Product Description: Disposable Medical Face Mask (non-sterile) Level 2 & Level 3**
- **Supplier Ref Number: SW-0614**
- **Product Country of Origin: China**
- **Product Name Submitted: Disposable Medical Face Mask**
- **Name of Reg. Authority: Intertek / POSI / EN / SGS**
- **Product Standards:**
    - **Intertek: No. GZHT02337923 ASTMF2100-19**
    - **POSI: ISO13485 : 2016 Cert**
    - **EN: No:20R000122MT Ver: DXAO-4144-34**
    - **SGS: HKTDR2020071080**
- **Product Mktg Lic Number: 9144030079920l4 4/02/07**
- **Product Shelf Life: 2yr**
- **Prod. Intended Use: Disposable Medical Face Mask**

CONTENT

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- FDA

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Photos Of The Sample

Package

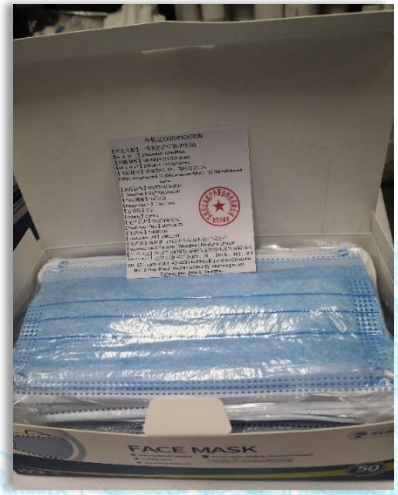
合格证CERTIFICATION

【产品名称】一次性使用口罩(非医用)
【N a m e】Disposable Face Mask
【规格型号】SW-0614 (17.5x9.5cm)
【M o d e l】SW-0614 (17.5x9.5cm)
【主要成分】无纺布67.5%、熔喷布32.5%
【Main components】67.5%non-woven fabric、32.5%melt-blown fabric
【执行标准】T/CTCA 7-2019
【Standard】T/CTCA 7-2019
【包装规格】50只/盒
【Packing Spec.】50pcs/box
【有效期】2年
【Validity】2 years
【生产日期】2020年7月21日
【Production Date】2020.07.21
【批次号】K200705Y
【Production LOT】K200705Y
【生产商】深圳市山而威户外装备科技有限公司
【Manufacturer】Sunway (Shenzhen) Products Limited
【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、201、301东、401、501
【Address】101, 201, east of 301, 401&501,Building E, junxuan Company, No.16 Yikui Road, Kuixin Community, Kuichong street, Dapeng new district, Shenzhen.

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Packaging Information

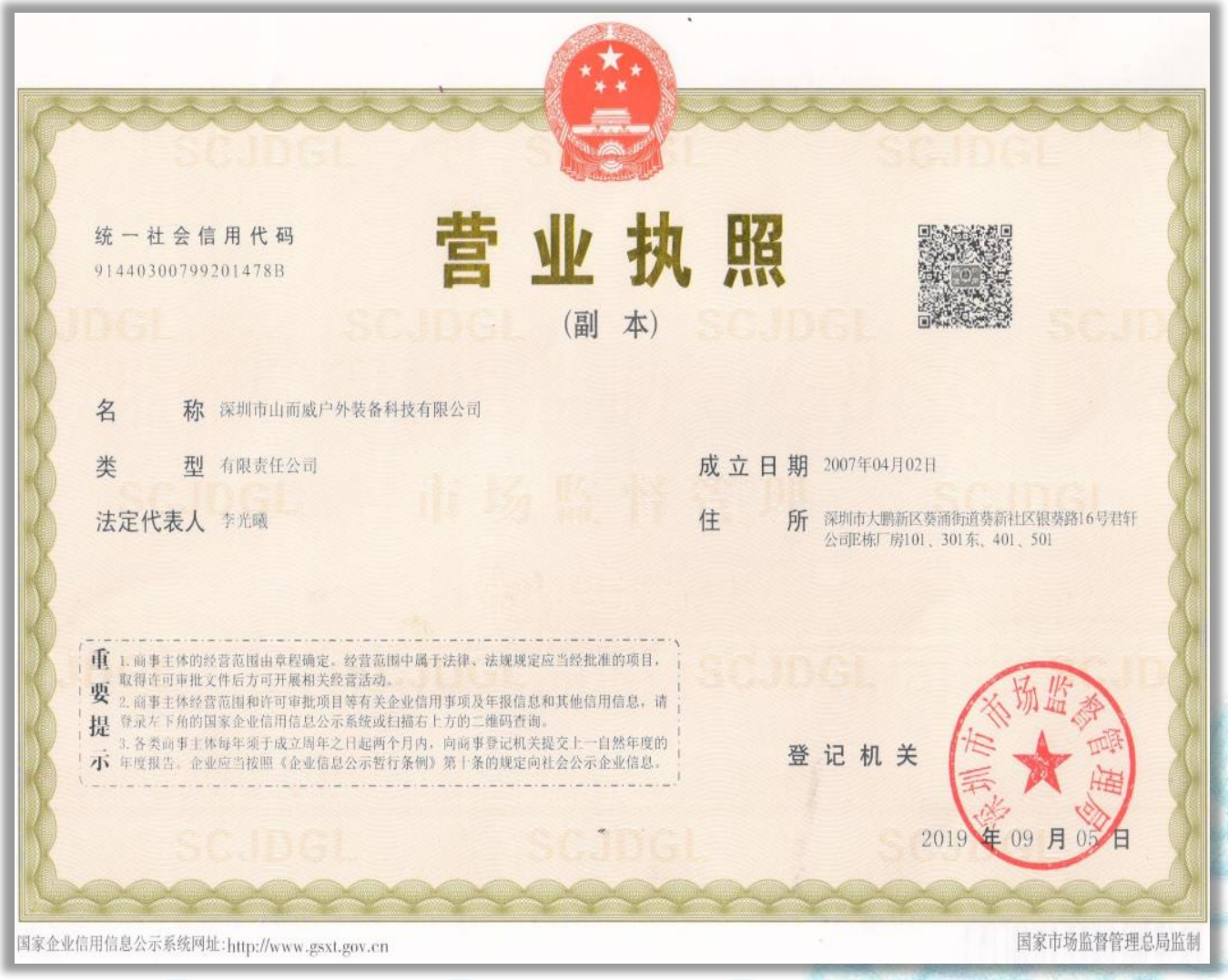
No.	Unit Package	Qty（Pcs）/Carton	Measurement			N.W. (KGS)	G.W. (KGS)
			Length (cm)	Width (cm)	Height (cm)		
1	50pcs/box	2000	47.00	42.00	35.00	8.00	9.00



Photos Of The Production Workshop

Photo Of The Company

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

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

深圳市市场监督管理局

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

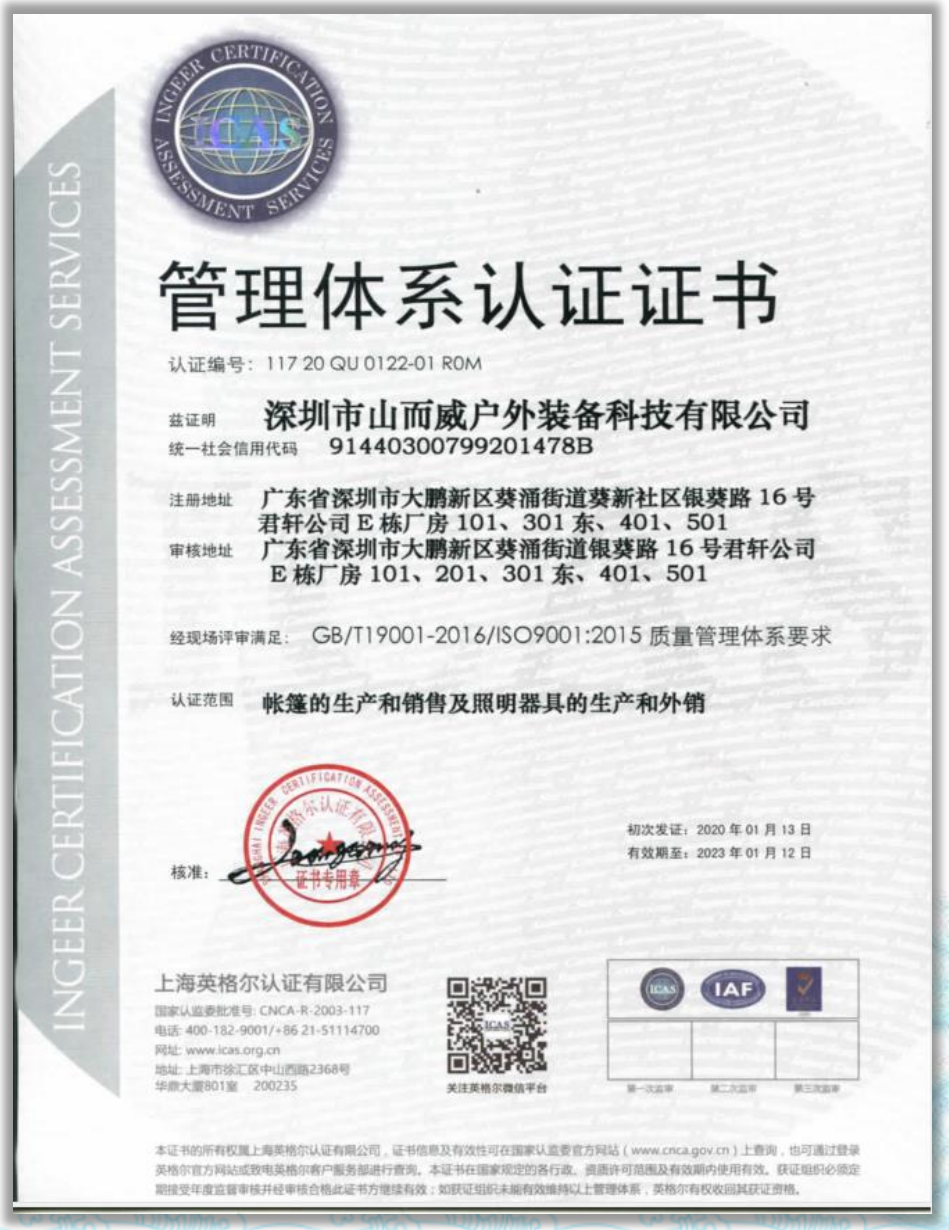
销售类型

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			

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company



INGEER CERTIFICATION ASSESSMENT SERVICES

INGEER CERTIFICATION ASSESSMENT SERVICES

ICAS

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：

证书专用章

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

ICAS　IAF

第一次监审　第二次监审　第三次监审

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业、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

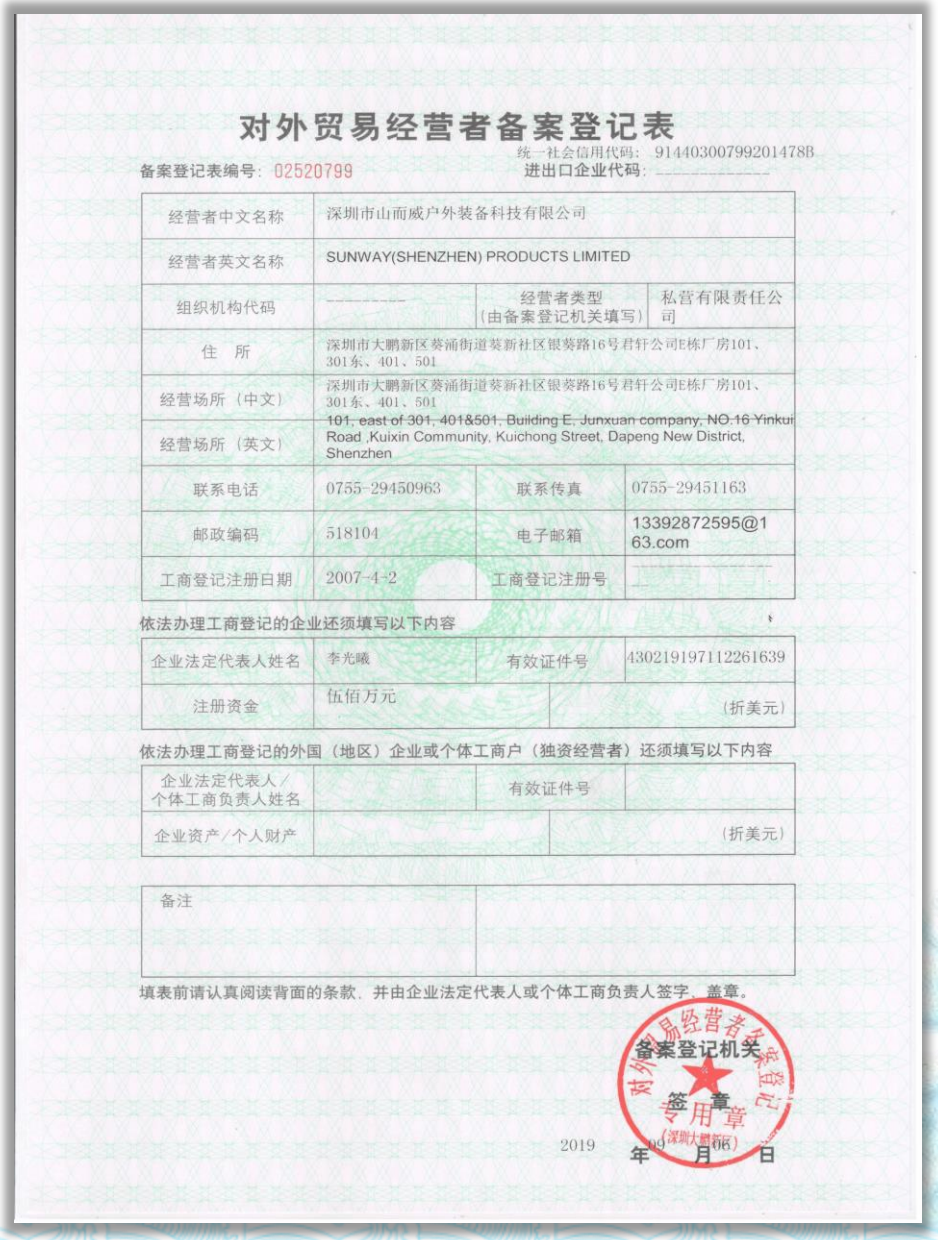
Expiry Date: 12 Jan. 2023

Shanghai Ingeer Certification Assessment Co.,Ltd.

IAF

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

CE Certificate

TXB

Certificate of Compliance

93/42/EU Protective Equipment

Certificate Number:	TXB20200310SY01
Applicant:	Sunway（shenzhen）Products Limited.
Address of Applicant:	101 east of 301,401&501,Building E junxuan company,No .16 yinkui Road, Kuixin Community,Kuichong street,dapeng new District,shenzhen
Manufacturer:	Sunway（shenzhen）Products Limited.
Address of Manufacturer:	101, 301 East, 401, 501,E Building , Junxuan Company, 16# Yinkui Road, Kuixin Community, Kui Chong Street, Dapeng District, Shenzhen,518119, China
Product Name:	Disposable Medical Face Mask
Trademark	SUN-V
Main Test Model:	SW-0614

Sufficient samples of the product have been tested and found to be in conformity with

Test Standard: EN 14683:2005

As Shown in the
Test Report Number: TXB20200310SY01

Conclusion

This Verification of Compliance has been issued on a voluntary basis.. TXB confirms that a Technical Construction File ((TCF)) is existent for the above listed product((s)).. The TCF satisfactorily covers the essentia requirements off the above listed Directive((s)).. Other relevant Directives have to be observed in case they are applicable.. This Document is only valid for the equipment and configuration described and in conjunction with the TCF detailed above.. Whereas the Manufacturer is responsible off the certification off the product((s)) and not exempted to perform all the necessary activities before placing the product((s)) on the market.. The Manufacturer is also responsible off the internal production control to ensure the product((s)) are in compliance with the essential requirements off the above mentioned Directive((s))

CE

Issued date:
Mar,10,2020

The certificate applies to the tested sample above-mentioned only and shall not imply an ass... of the... production. It is only valid in connection with the test report above-mentioned. Copyright of this ... owned by TXB and may not be reproduced other than in full and with the prior approval of the General Manager.

TXB Rheinland Testing Services Corp Limited
E-mail: tacy@xb-lab.com www.xb-lab.com

SUNWAY (SHENZHEN) PRODUCTS LIMITED

CE Notification Confirmation

Sungo

CE Notification Confirmation

This is to confirm that, according to the council directive 93/42/EEC (MDD), SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

SUNWAY (SHENZHEN) PRODUCTS LIMITED
101,East of 301,401&501,Building E, Junxuan Company,No.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, 518119,China

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

According to 93/42/EEC (MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration number.

Disposable Medical Face Mask
Class I according to Annex IX of 93/42/EEC
GMDN: 35177
CIBG Number: NL-CA002-2020-50600

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 document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00238
Issue date: May.08, 2020

SUNGO Europe B.V.
Olympisch Stadion 24,1076DE
Amsterdam, Netherlands
ec.rep@sungogroup.com

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Authorised Signature
Only used for the EU Representative Signature

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

EN Test Report

No:20R000122MT

Ver: DXAO-4144-34

Test Report (Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: DXAO-4144-34

No:20R000122MT Issue Date: 2020-07-20

Applicant: SUNWAY (SHENZHEN) PRODUCTS LIMITED

Address: 101, 201, EAST OF 301, 401&501, BUILDING E, JUNXUAN COMPANY, NO.16 YINKUI ROAD, KUIXIN COMMUNITY, KUICHONG STREET, DAPENG NEW DISTRICT, SHENZHEN, 518119, CHINA

Information confirmed by applicant:

Disposable medical face mask(non-sterile)

Quantity: eighty pieces

Lot number: 20200410

Model: SW-0614

Size: 175mm×95mm

Classification: Type IIR

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-04-22

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M
Materials and construction	M
Design	M
General	M

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

Remark:
Modified content: modified applicant address.
This report replaces test report 20R000122MO which has become invalid automatically.
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: Zishan Guo

ZiShan Guo Senior Engineer

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

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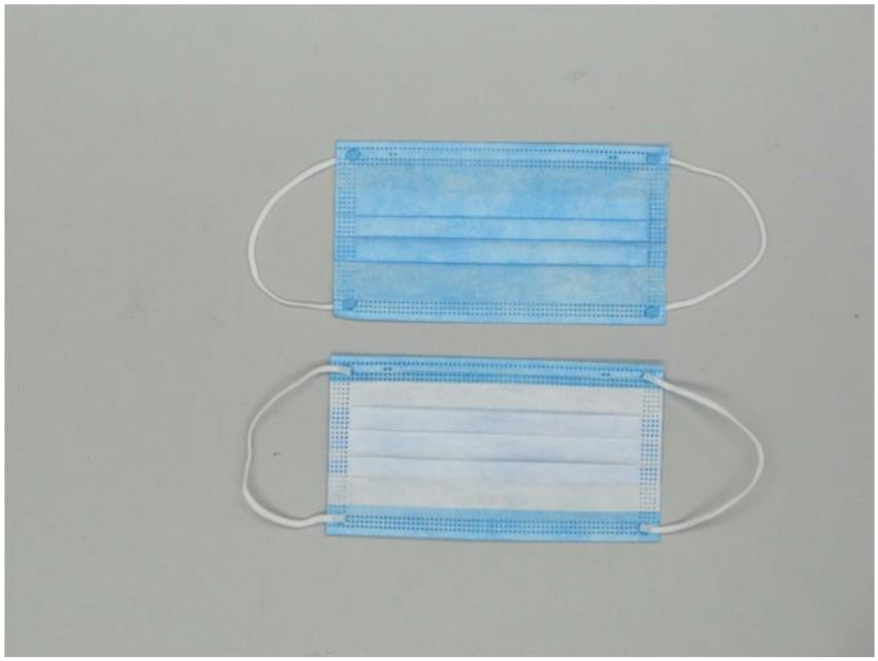
EN Test Report

No:20R000122MT
Ver: DXAO-4144-34

Test Report (Electronic version)

No: 20R000122



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EN Test Report

No:20R000122MT
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Test Report

(Electronic version)

No: 20R000122

Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 50.5%
Culture medium: TSA agar medium
Culture temperature: 37℃, Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^{5} CFU /ml
Positive control average (C): 1.9×10^{3} CFU
Negative monitor count: ＜1 CFU
Test area: 40 cm^{2}
Dimensions of the test specimens: 15cm×15cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

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Test Report

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Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	21	98.89	≥98 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	27	98.58			
3	25	98.68			
4	17	99.11			
5	31	98.37			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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Microbial cleanliness

Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:

Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 μm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:

Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

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Results:

Microbial	Measured value (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
Bacteria	25	28	≤30 EN 14683:2019+AC:2019	Type ⅡR	Pass
Fungi	3				

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EN Test Report

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Test Report

(Electronic version)

No: 20R000122

Differential pressure
Test method: EN 14683:2019+AC:2019 Annex C

Test principle:
This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:
GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:
Air flow: 8 l/min
Test area: 4.9cm^2
Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
General location of the areas of the mask the differential measurements: specimen center

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EN Test Report

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Results:

Sample	Measured value (Pa)	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	Classification	Conclusion
1	88	18.0	<60 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	82				
3	80				
4	95				
5	93				
Average	88				

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Splash resistance pressure

Test method: ISO 22609:2004

Test principle:

A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario. Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa. Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

Test equipment:

Test apparatus for synthetic blood penetration LFY-227
Air compressor
Graduated cylinder
Electronic balance
Targeting plate

The environmental conditions of the laboratory and test condition:

Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Surface tension of synthetic blood: 0.042 N/m
Pressure: 16.0 kPa
Velocity: 550 cm/s

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Test Report

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No: 20R000122

Results:

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass			
18	pass			
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
29	pass			
30	pass			
31	pass			
32	pass			
Final result	pass			

Remarks:

An acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

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Materials and construction

Test Method: EN 14683:2019+AC:2019 5.1.1

Results:

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Pass
The medical face mask shall not disintegrate, split or tear during intended use.	Pass
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Pass

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Test Report

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No: 20R000122

EN Test Report

No:20R000122MT

Ver: DXAO-4144-34

Design

Test Method: EN 14683:2019+AC:2019 5.1.2

Results:

Requirement	Conclusion
The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	**Pass**
Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	**Pass**

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Test Report

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No: 20R000122

EN Test Report

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General

Test Method: EN 14683:2019+AC:2019 5.2.1

Results:

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	Pass

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———End of Report———

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Test Report

No. GZHT02337923

ASTMF2100-19

Report Ref:	GZHT02337923		
Date Received:	Sep 14, 2020	**Date Issued:**	Oct 09, 2020

Company Name:	SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address:	101, 201、EAST OF 301、401 &501 BUILDING E, JUNXUAN COMPANY NO.16 YINKUI ROAD, KUIXIN COMMUNITY KUICHONG STREET, DAPENG NEW DISTRICT, SHENZHEN, CHINA
Contact Name:	王勤

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Medical Face Mask
Ratings	:	Level 3
Sample Name	:	Disposable Medical Face Mask
No. Of Sample	:	One(100 pieces)
Size	: -	
Colour	:	Blue
Standard	:	ASTM F2100-19$^{\varepsilon 1}$
Date received/ Test Started	:	Sep 14, 2020
Ref	:	Type No.: SW-0614

Test was conducted on specific items, at our client's request.

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

Lin Lin
General Manager

HTJ2337923

QIN / hilaryxu

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Number: GZHT02337923

Test Report

No. GZHT02337923
ASTMF2100-19

Original Sample Photo


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

Lin Lin
General Manager

QIN / hilaryxu

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Test Report

No. GZHT02337923
ASTMF2100-19

Summary of testing:

With reference to following standard:
ASTM F2100-19$^{\varepsilon 1}$ Standard Specification for Performance of Materials Used in Medical Face Masks Level 3

Materials Used in The Submitted Sample Were Found To Comply With The Level 3 Requirements of ASTM F2100-19$^{\varepsilon 1}$with respect to Bacterial Filtration Efficiency (BFE), Differential Pressure, Sub-Micron Particulate Filtration, Resistance to Penetration by Synthetic Blood and Flammability tests.

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

Lin Lin
General Manager

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Number: GZHT02337923

Tests Conducted (As Requested By The Applicant)

Test Report

No. GZHT02337923

ASTMF2100-19

1 Differential Pressure (ASTM F2100-19[e1], Section 9.2, Testing Refer to EN 14683:2019+AC:2019 Annex C): Air flow: 8L/min, Test Area Diameter 25 mm, Test Area: 4.9 cm^2 .

Tested Sample	Result (mm H_2O/cm^2)*					Performance Requirement for Medical Face Mask (mm H_2O/cm^2)	
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5		
Location 1	5.4	6.0	5.2	6.1	5.4	Level 3	<6.0
Location 2	5.1	5.6	6.8	6.3	5.4		
Location 3	6.2	5.6	6.6	6.0	6.1		
Location 4	5.9	5.6	6.0	6.3	6.5		
Location 5	6.1	6.2	5.1	5.0	5.8		
Average	5.7	5.8	5.9	5.9	5.8		
* = All the locations were evenly taken from the main mask body.							

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Number: GZHT02337923

Tests Conducted (As Requested By The Applicant)

Test Report

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ASTMF2100-19

2 Resistance to Penetration by Synthetic Blood (ASTM F2100-19[i] , Section 9.4, Testing Refer to ASTM F1862/F1862M-17, Test Pressure: 160 mmHg, Velocity: 635 cm/s):
Condition test specimens for a minimum of 4 hours in an environment of temperature (21±5) °C and relative humidity (85±5)% and conduct the test within 1 minute of removal from conditioning chamber.
Test Environment Condition: Temperature 24.0°C, Relative Humidity 86.0%

Tested Sample	Observation	Pass/Fail	Performance Requirement for Medical Face Mask Level 3: No Penetration at 160 mm Hg
Specimen (1)	No penetration	Pass	
Specimen (2)	No penetration	Pass	
Specimen (3)	No penetration	Pass	
Specimen (4)	No penetration	Pass	
Specimen (5)	No penetration	Pass	
Specimen (6)	No penetration	Pass	
Specimen (7)	No penetration	Pass	
Specimen (8)	No penetration	Pass	
Specimen (9)	No penetration	Pass	
Specimen (10)	No penetration	Pass	
Specimen (11)	No penetration	Pass	
Specimen (12)	No penetration	Pass	
Specimen (13)	No penetration	Pass	
Specimen (14)	No penetration	Pass	
Specimen (15)	No penetration	Pass	
Specimen (16)	No penetration	Pass	
Specimen (17)	No penetration	Pass	
Specimen (18)	No penetration	Pass	
Specimen (19)	No penetration	Pass	
Specimen (20)	No penetration	Pass	
Specimen (21)	No penetration	Pass	
Specimen (22)	No penetration	Pass	
Specimen (23)	No penetration	Pass	
Specimen (24)	No penetration	Pass	

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Tests Conducted (As Requested By The Applicant)

Test Report
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Specimen (25)	No penetration	Pass
Specimen (26)	No penetration	Pass
Specimen (27)	No penetration	Pass
Specimen (28)	No penetration	Pass
Specimen (29)	No penetration	Pass
Specimen (30)	No penetration	Pass
Specimen (31)	No penetration	Pass
Specimen (32)	No penetration	Pass
Conclusion*:		**Accepted**

* = An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

3 Sub-Micron Particulate Filtration (ASTM F2100-19[1], Section 9.3,Testing Refer to ASTM F2299/F2299M-17):

Particle size in aerosol: 0.1 μm, Aerosol: Polystyrene Latex Spheres (PSL), Test area: 100 cm^2, Airflow: 5.33 cm/s, Sampling time: 1 min.

Laboratory Condition: Temperature 21.0°C, Relative Humidity 47.0%

Tested Sample/Component	Result (%)	Performance Requirement for Medical Face Mask (%)
Specimen (1)	99.3	Level 3: ≥98
Specimen (2)	99.4	
Specimen (3)	99.5	
Specimen (4)	98.7	
Specimen (5)	98.8	

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Test Report

No. GZHT02337923
ASTMF2100-19

4 Flammability Test (ASTM F2100-19[1], Section 9.5, Testing Refer to 16 CFR Part 1610 (As Amendment In 2008)):

X	Plain Surface		Raised Surface

Burn Direction :	6 Length .Width
Prelim Plain Surface :	
Length: IBE	
Width: DNI	
Original* (seconds)	Requirement Class 1
1. IBE	
2. IBE	
3. DNI	
4. DNI	
5. DNI	
6. -	
7. -	
8. -	
9. -	
10. -	
Average : -	

Classification :	6	Class 1, Normal Flammability
	…	Class 2, Intermediate Flammability, Raised Surface
	…	Class 3, Rapid And Intense Burning

Explanation Of Flammability Results:	
DNI	Did not ignite.
IBE	Ignited but extinguished.

* The disposable fabrics and garments need not to be refurbished in accordance with 16 CFR Part 1610.35 (a)(2).

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Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663
Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & Technological Development District, Guangzhou, China
中国广州经济技开发区开发大道 235号恒运大厦 3楼
Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

Tests Conducted (As Requested By The Applicant)

Test Report

No. GZHT02337923

ASTMF2100-19

5 Bacterial Filtration Efficiency (BFE)

As per ASTM F2100-19^{e1} Standard Specification for Performance of Materials Used in Medical Face Masks Section 9.1 and ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.

Test Item	Results (%)					Performance Requirement for Medical Face Mask (%)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	99.9	99.9	99.9	>99.9	>99.9	Level 3: ≥ 98

Remarks:
1. Biological Aerosol: Staphylococcus aureus (ATCC 6538).
2. Testing side: Inside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm^2
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2.6×10^8 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

This item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

End of Report

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
中国广州经济技术开发区科学城彩频路 7号之二第 1－8层 02房、01房、101、E201、E301、E401、E501、E601、E701、E801
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Test Report

HKTDR2020071080

SGS

Technical Documentation Review Report
Date: 23 Jul 2020

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SUNWAY (SHENZHEN) PRODUCTS LIMITED
101, 201, East of 301, 401 &501, Building E, Jurouan Company, No.16 Yinkui Road, Kuisin Community, Kuichong Street, Dapeng New District, Shenzhen, 518119, China

The documentation was submitted by the client for the product as: **Disposable medical face mask (non-sterile)**

SGS Job No.	:	GZHL2006034257MD
Model/Type	:	SW-0614
Manufacturer	:	SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address of Manufacturer	:	101, 201, East of 301, 401 &501, Building E, Jurouan Company, No.16 Yinkui Road, Kuisin Community, Kuichong Street, Dapeng New District, Shenzhen, 518119, China
Country of Origin	:	CHINA
Country of Destination	:	Europe
Date of Documentation Received	:	23 Jul 2020
Review Period	:	23 Jul 2020 - 24 Jul 2020
Service Requested	:	Review the completeness of the Technical Documentation in accordance with the requirements of Annex VII of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices and its amendments as well as relevant harmonized standards.
Review Summary	:	Based on the submitted documentation, this is to conclude that non-compliance or missing information was not identified according to the requirements of Annex VII of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices and its amendments as well as relevant harmonized standards. Please note that no sample is provided for review and no testing is carried out in this service.
Date of Expiry	:	23 Jul 2021 (1 year)

DISCLAIMER - PLEASE READ

While all due care and skill were exercised in carrying out this review, SGS Hong Kong Ltd (SGS) accepts responsibility only for proven gross negligence. Considering that the situation surrounding COVID-19 is evolving, the findings provided in this report may change on a daily basis. This report relates only to the submitted documentation. The authenticity of the documentation reviewed by SGS, and the consistency of the product and the documentation is not covered. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the production and quality control of the product(s). This report is not a legal document and cannot be used as such. This is not a legal interpretation of the law. Reliance should be placed on the wording of the legislation itself. SGS may have extracted from the compiled data specific criteria which are not intended to be the substitute of the relevant legislation and/or standards.

Signed for and on behalf of
SGS Hong Kong Ltd

Ivan CHAN
Vice President – R & D and Innovation

Test Report

HKTDR2020071080

SGS

Technical Documentation Review Report
Date: 23 Jul 2020

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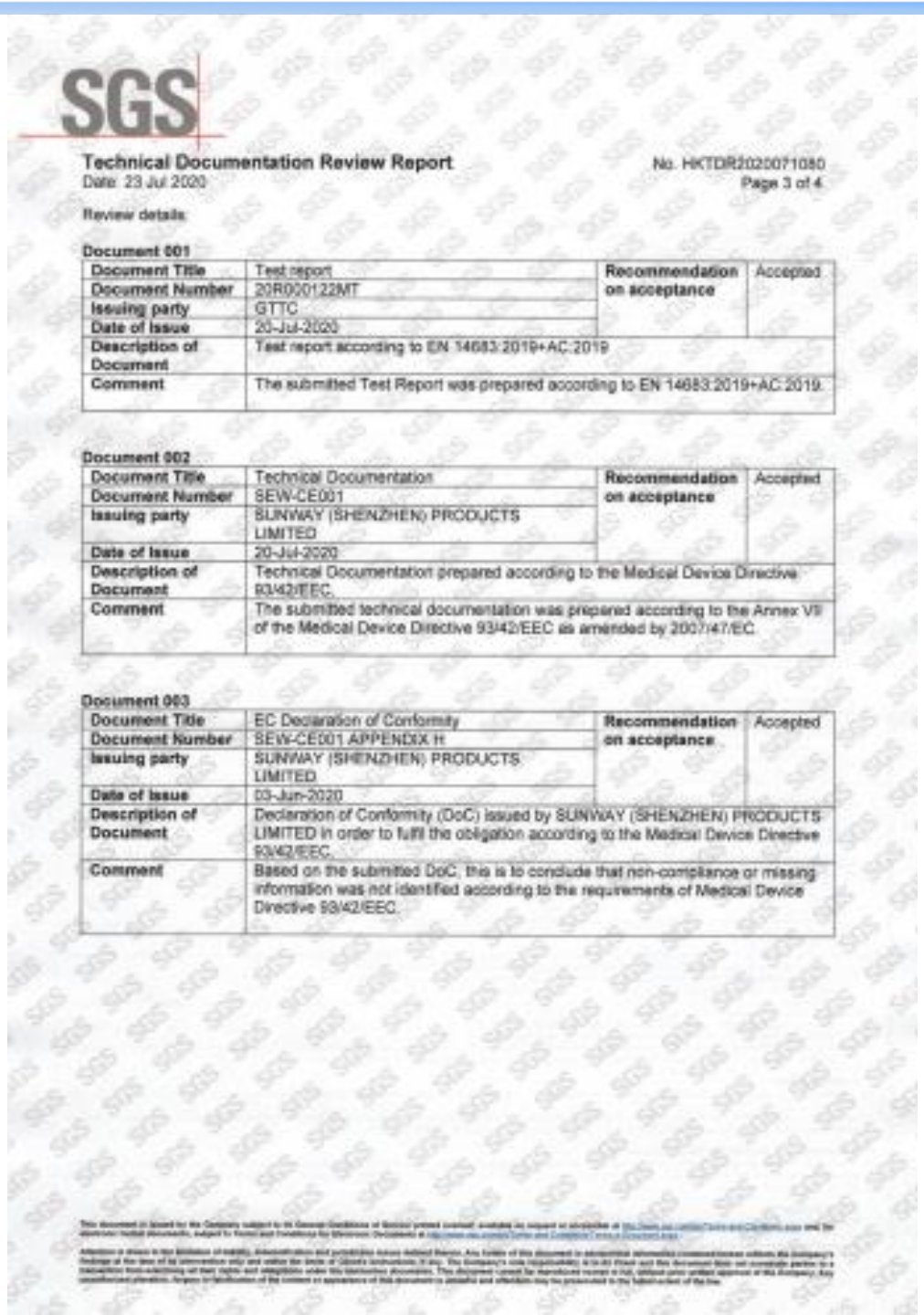
Product photo:

Product packaging and label artwork:

Test Report

HKTDR2020071080



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Technical Documentation Review Report
Date: 23 Jul 2020

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Review details

Document 001

Document Title	Test report	**Recommendation on acceptance**	Accepted
Document Number	20R000122MT		
Issuing party	GTTC		
Date of Issue	20-Jul-2020		
Description of Document	Test report according to EN 14683:2019+AC:2019		
Comment	The submitted Test Report was prepared according to EN 14683:2019+AC:2019.		

Document 002

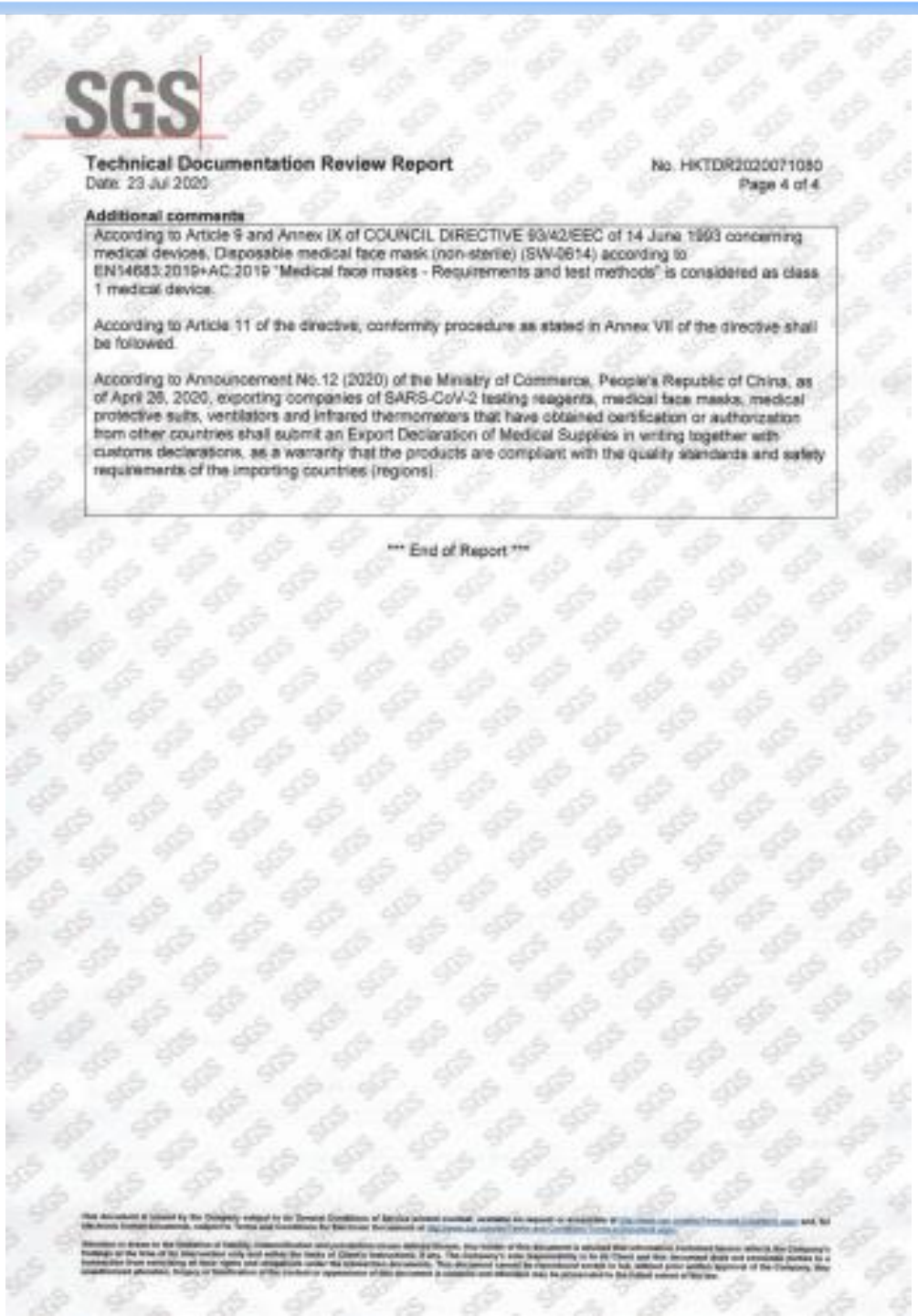
Document Title	Technical Documentation	**Recommendation on acceptance**	Accepted
Document Number	SEW-CE001		
Issuing party	SUNWAY (SHENZHEN) PRODUCTS LIMITED		
Date of Issue	20-Jul-2020		
Description of Document	Technical Documentation prepared according to the Medical Device Directive 93/42/EEC.		
Comment	The submitted technical documentation was prepared according to the Annex VII of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.		

Document 003

Document Title	EC Declaration of Conformity	**Recommendation on acceptance**	Accepted
Document Number	SEW-CE001 APPENDIX H		
Issuing party	SUNWAY (SHENZHEN) PRODUCTS LIMITED		
Date of Issue	03-Jun-2020		
Description of Document	Declaration of Conformity (DoC) issued by SUNWAY (SHENZHEN) PRODUCTS LIMITED in order to fulfil the obligation according to the Medical Device Directive 93/42/EEC.		
Comment	Based on the submitted DoC, this is to conclude that non-compliance or missing information was not identified according to the requirements of Medical Device Directive 93/42/EEC.		

Test Report

HKTDR2020071080



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Technical Documentation Review Report

Date: 23 Jul 2020

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Additional comments

According to Article 9 and Annex IX of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Disposable medical face mask (non-sterile) (SW-0614) according to EN14683:2019+AC:2019 "Medical face masks - Requirements and test methods" is considered as class 1 medical device.

According to Article 11 of the directive, conformity procedure as stated in Annex VII of the directive shall be followed.

According to Announcement No.12 (2020) of the Ministry of Commerce, People's Republic of China, as of April 28, 2020, exporting companies of SARS-CoV-2 testing reagents, medical face masks, medical protective suits, ventilators and infrared thermometers that have obtained certification or authorization from other countries shall submit an Export Declaration of Medical Supplies in writing together with customs declarations, as a warranty that the products are compliant with the quality standards and safety requirements of the importing countries (regions).

*** End of Report ***

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

Certification of FDA Registration Service

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

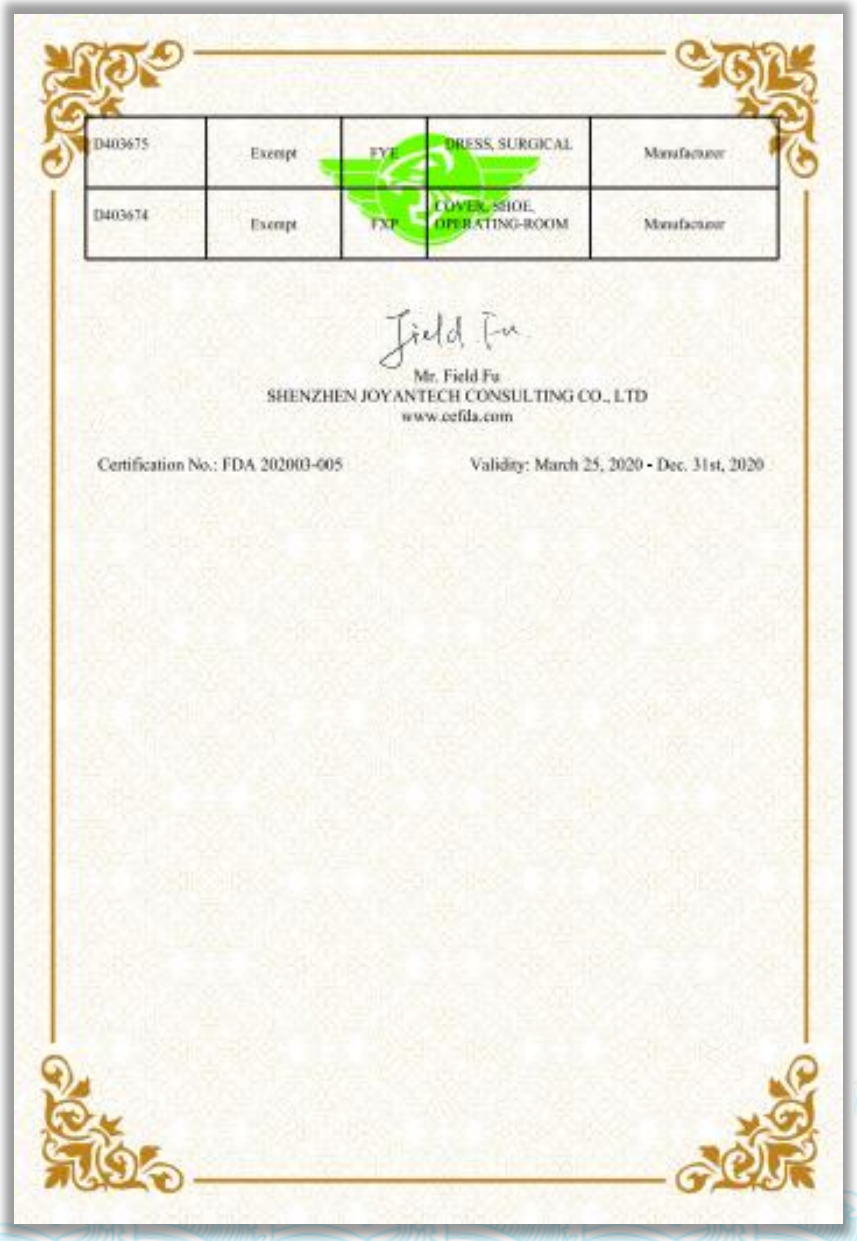
Establishment: SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address: E Building,Junxuan company,16# Yinkui Road, Kuixin community, Kuichong street,Dapeng New District, Shenzhen, Guangdong, 518119, CHINA

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

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

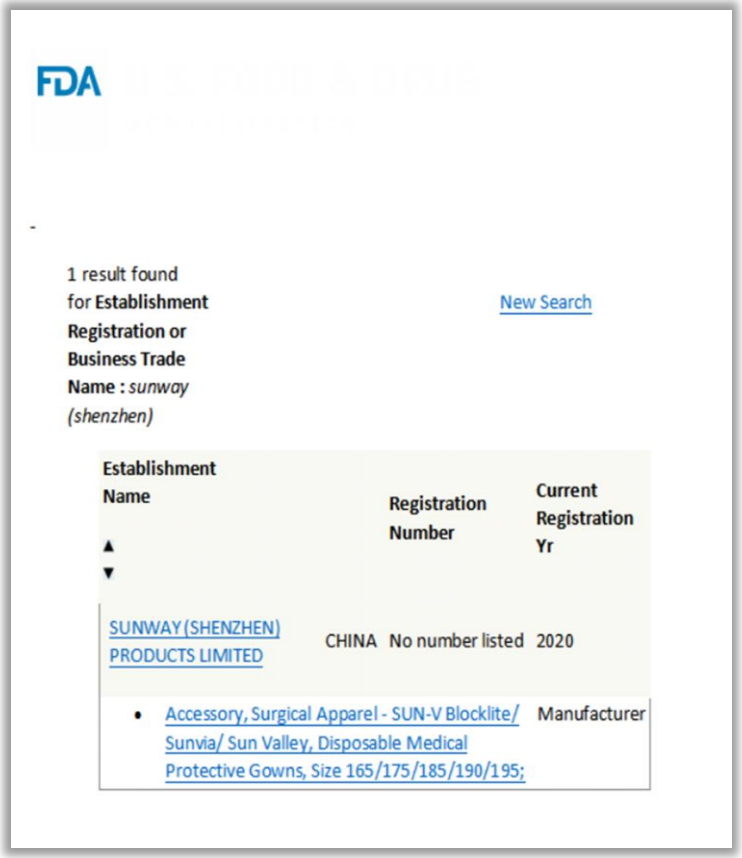
Business Trade Name : *sunway (shenzhen)*
Establishment Registration or FEI Number : *3014331592*

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



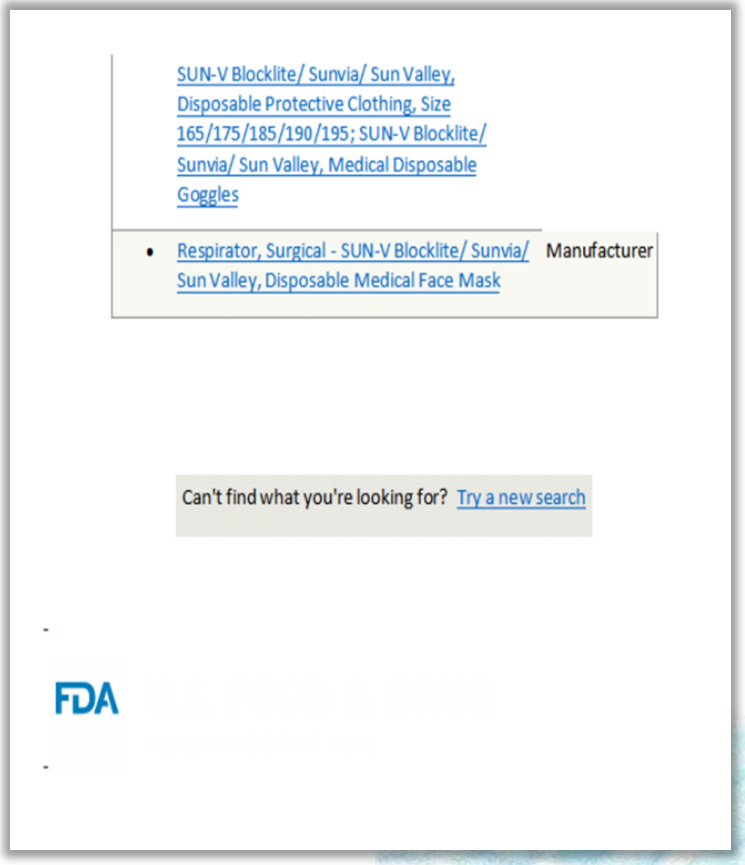
FDA U.S. FOOD & DRUG ADMINISTRATION

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

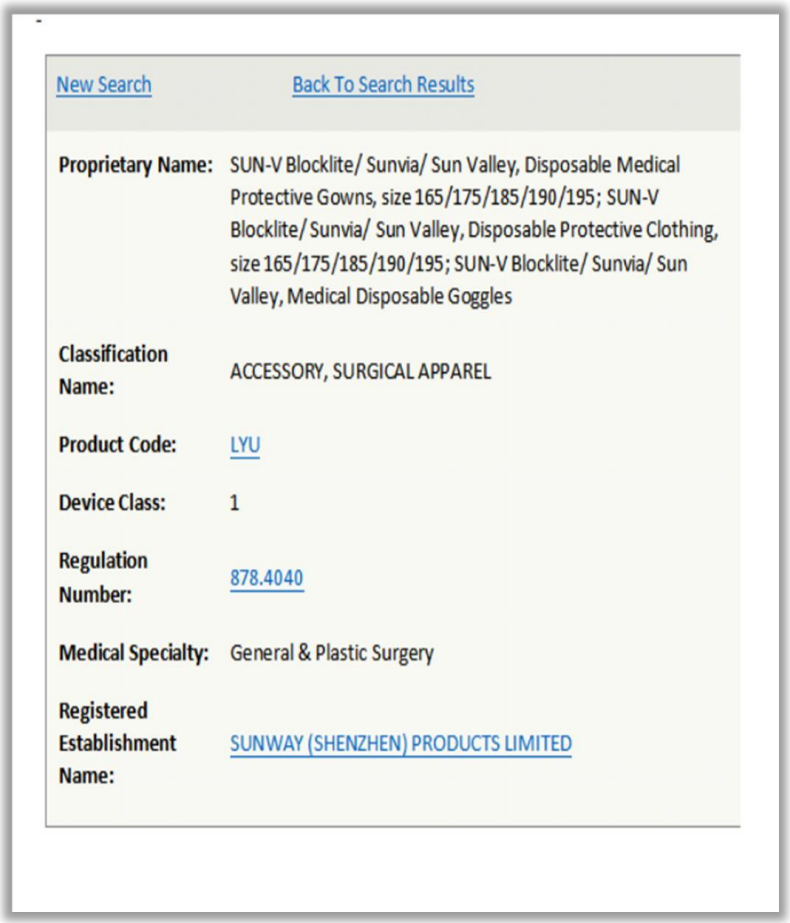
- Respirator, Surgical - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Face Mask — Manufacturer

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

FDA U.S. FOOD & DRUG ADMINISTRATION

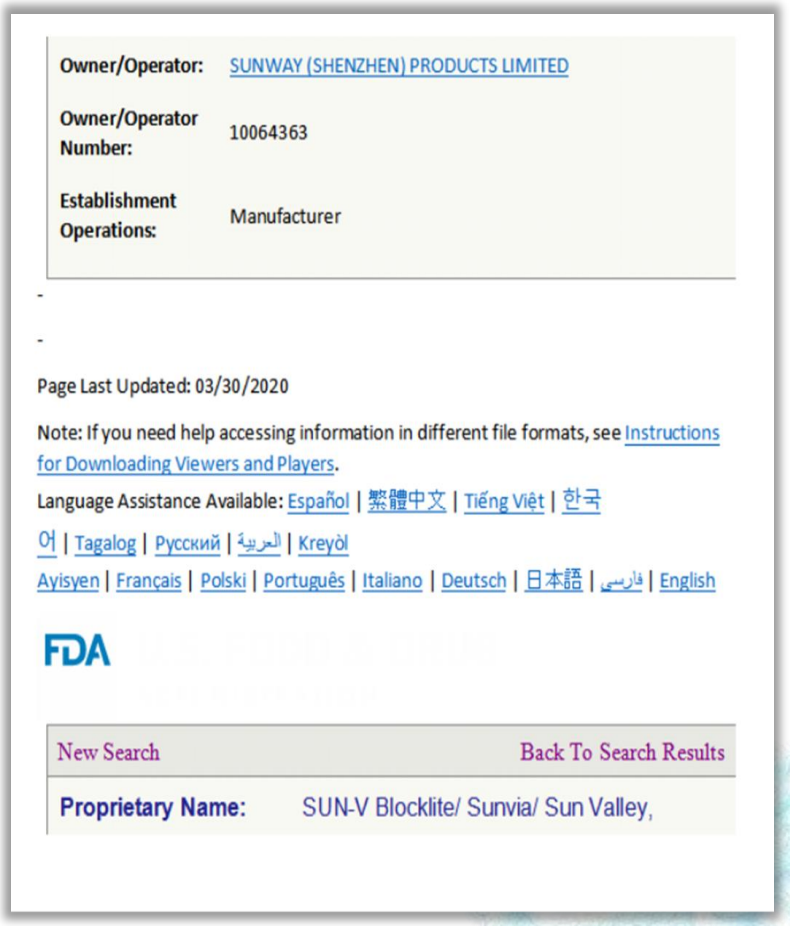
SUNWAY (SHENZHEN) PRODUCTS LIMITED

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

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FDA

New Search Back To Search Results

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

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA