



Disposable Isolation Gown

TUV Level 2 Disposable Isolation Gown



取得国取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization From other Countries

	生产企业	统一社会信用代码	国外注册 认证情况
二、	医用防护服 Medical Protective Gowns		
200	福建顺邦防护科技有限公司 Fujian Safetech Protection Co.,Ltd	91110115596057832U	欧盟CE

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CHINESE MANUFACTURER



SAFETECH PROTECTION

Address: No.6 road east, Tieling industrial zone, Zone 1,
block 9 Jingxi town. Minhou county Fuzhou, Fujian province, P.R. China

Tel.: +86-591-8780 7888 Fax.: +86-591-8782 6099

Web: <http://www.spsafetech.com>

E-mail: infosafetech@spsafetech.com

Medical device production license

医疗器械生产许可证

License no.: Bureau of Fujian medical device supervision #20200618

许可证编号：闽药监械生产许20200618号

企业名称：福建顺邦防护科技有限公司

Company name: Fujian safetech protection co.,ltd

生产地址：

福州市闽侯县荆溪镇铁岭工业园一期
The first floor of building #1, building #2 and building #9, No.6 road east,
Tieling Industrial zone, Zone 1,Block 9,Jingxi town, Minhou county,

法定代表人：刘玉林

Legal representative: Liu Yulin

生产范围：

Production scope:
class II 14-14 protective equipment for medical staff

企业负责人：刘玉林

Business owner: Liu Yulin

住所：闽侯县铁岭工业集中区

发证部门：

福建省药品监督管理局

Address: Tieling industrial concentration area,Minhou county

有效期限：至 2025 年 06 月 03 日

发证日期：

2020 年 06 月 04 日

Valid to :2025-JUNE-03

Date of Issue:2020-JUNE-04



国家药品监督管理局制

State food and drug administration

LEVEL 2 Blue TUV LEVEL 2 Disposable isolation gown



FDA
10063359

Product description

- Polypropylene Gowns Offer Excellent Fluid Protection for Worry-Free Job Performance
- Made from blue polyethylene-coated polypropylene material
- Gowns provide a high level of fluid protection
- Waist and neck ties ensure that gowns remain securely in place
- Available in open or closed back with Rib knit cuffs

SIZE INFORMATION

FREE SIZE	Chest(CM)	Height(CM)
SIZE	75	142

Knitted cuffs



Ultrasonic sewing



Isolation gown

Product	Disposable Isolation Gown
Style NO	SPFH-GL008B
Material	Fabric: Multilayer SMS fabric, 56gsm
	Anti-static, Alcohol Resistant
	Weight: 35gsm
Color	Blue
Sizing	An appropriate size should be selected

Impervious Isolation Gowns — Coated Polypropylene

The Single Use Bilaminated Isolation Gowns are impervious and suitable for procedures with high risks of exposure to fluids.

Report No.: 244242917a 001
Client: FUJIAN SAFETECH PROTECTION CO.,LTD
Contact Information: No.6 Road East,Tieling Industrial Zone,zone 1, block 9, jingxi town, Minhou county
Contact Person: Peter Xie

Sample Description as Declared:

No. Of Sample : One(1)
Product Description : Disposable Isolation Gown
Material : PP
Colour : Blue
Style No. : SPFH-GL008B
Country of Origin : -
Manufacturer's Name : -

Applicant's Provided Care Instruction/Label: -

Sample Receiving date: 2020-06-03
Testing Period: 2020-06-03 to 2020-06-10

For and on behalf of
TÜV Rheinland (Shanghai) Co., Ltd.



2020-06-11 Joyce Zhou / Assistant Technical Manager

Date Name/Position

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

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Conclusion:

M001

Liquid Barrier Performance and
Classification of Protective Apparel and
Drapes Intended for Use in Health Care
Facilities (ANSI/ AAMI PB70-2012)

*

Note:

P = Pass

F = Fail

I = Inconclusive

F# = Composite Fail

= No Comment

- = Did Not Perform

N/A = Not Applicable

Remark:*The results shown in this test report refer to the samples tested only, unless otherwise stated. For further details, please refer to the following page(s).

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Material List:

Material No.	Material	Color	Location
M001	Whole Product	Blue	Disposable Isolation Gown

www.safetech.com

Test Report No.: 244242917a001

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1. Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities (ANSI/ AAMI PB70-2012)
Section 4.2.1 Water Resistance: Impact Penetration Test

Test method : AATCC TM 42-2017

M001

<u>As Received</u>	Weight of blotter gained (g)				
Specimen	1	2	3	4	5
Area A (Critical zone-front)	0	0.2	0	0	0
Area B (Critical zone-sleeve)	0	0.1	0	0	0
Area C (Critical zone-back)	0	0	0	0	0
Seam between areas A&B	0	0	0	0.1	0
Seam between areas A&C	0	0.1	0	0	0.1
Seam between areas B&C	0.1	0	0	0.1	0
Level	3	3	3	3	3
Remark: 1) Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5 grams(g) 2) Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g) 3) Level 3: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)					

Section 4.2.1 Water Resistance: Hydrostatic Pressure Test

Test method : AATCC TM 127-2018

Tested side : Face

Water condition : 21 °C distilled water

Gradient : 60 mbar/min

M001

<u>As Received</u>	Water Column (cmH ₂ O)				
Specimen	1	2	3	4	5
Area A (Critical zone-front)	>50	>50	>50	>50	>50
Area B (Critical zone-sleeve)	>50	>50	>50	>50	>50
Area C (Critical zone-back)	>50	>50	>50	>50	>50

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Seam between areas A&B	>50	>50	>50	>50	>50
Seam between areas A&C	36.4	41.5	40.1	>50	30.1
Seam between areas B&C	>50	>50	>50	>50	>50
Level	2	2	2	3	2
Remark: 1) Level 2: all critical zone components shall have a hydrostatic resistance of at least 20 cmH ₂ O 2) Level 3: all critical zone components shall have a hydrostatic resistance of at least 50 cmH ₂ O					

Barrier Performance of Each Specimen and Final Classification Commended

Specimen	Level				Classification	Final Classification
	Impact Penetration Test AATCC 42	Hydrostatic Pressure Test AATCC 127	Resistance to Bacteriophage Phi-X174 ASTM F1671	Resistance to synthetic blood ASTM F1670		
1	3	2	/	N/A	Level 2	Level 2
2	3	2	/	N/A	Level 2	
3	3	2	/	N/A	Level 2	
4	3	3	/	N/A	Level 3	
5	3	2	/	N/A	Level 2	

Remark:

The barrier performance of all critical zone components, including seams and points of attachments shall be determined. The classification of isolation gown shall be a number denoting the performance of the critical zone component having the lower barrier performance.

Level	Test	Requirement
1	AATCC TM 42	≤ 4.5g
2	AATCC TM 42 AATCC TM 127	≤ 1.0g ≥ 20cmH ₂ O
3	AATCC TM 42 AATCC TM 127	≤ 1.0g ≥ 50cmH ₂ O
4	Drapes and Drape Accessories: ASTM F 1670 Surgical and the Protective Apparel: ASTM F 1671	Pass Pass

N/A= Not applicable.

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Sample Photos



Front



Back

- END -

Classification Name:NON-SURGICAL ISOLATION GOWN

Registered Establishment Name:FUJIAN SAFETECH PROTECTION CO., LTD

Registered Establishment Number:**3016666730**

Owner/Operator:Fujian Safetech Protection Co Ltd

Owner/Operator Number:**10063359**

Establishment Operations:Manufacturer



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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SEARCH

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search		Back To Search Results
Classification Name:	NON-SURGICAL ISOLATION GOWN	
Product Code:	QEA	
Device Class:	1	
Regulation Number:	878.4040	
Medical Specialty:	General & Plastic Surgery	
Registered Establishment Name:	FUJIAN SAFETECH PROTECTION CO., LTD	
Registered Establishment Number:	3016666730	
Owner/Operator:	Fujian Safetech Protection Co Ltd	
Owner/Operator Number:	10063359	
Establishment Operations:	Manufacturer	

Page Last Updated: 05/04/2020
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U.S. Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, MD 20993
 Ph. 1-888-INFO-FDA (1-888-463-6332)
 Contact FDA

Combination Products
 Advisory Committees
 Science & Research
 Regulatory Information
 Safety
 Emergency Preparedness

U.S. Department of Health & Human Services

USA.gov

福建省福州市 第一类医疗器械生产备案凭证

备案编号：闽榕食药监械生产备20200001号

企业名称	福建顺邦防护科技有限公司			
住 所	福建省福州市闽侯县荆溪镇铁岭工业集一期九号东路六号			
生产地址	福建省福州市闽侯县荆溪镇铁岭工业集一期九号东路六号			
法定代表	刘玉林	企业负责人	刘玉林	
生产范围	《医疗器械分类目录》（2002版）一类：6864 《医疗器械分类目录》（2017版）一类：14			
生产产品 列表	产品名称	产品备案号	登载日期	备注
	隔离衣	闽榕械备20200009号	2020年2月17号	

备案部门： 福州市市场监督管理局
 备案日期： 2020年02月17日



福建省福州市 第一类医疗器械备案凭证

福建顺邦防护科技有限公司：

根据相关法规要求，对你单位第一类医疗器械：隔离衣
/14-14-03 注输、护理和防护器械予以备案，备案号：闽榕械备
20200009 号。


福州市市场监督管理局

日期：2020年02月17日



第一类医疗器械备案信息表

备案号：闽榕械备 20200009 号

备案人名称	福建顺邦防护科技有限公司
备案人组织机构代码	793752244
代码	
备案人注册地址	福建省福州市闽侯县荆溪镇铁岭工业集一期九号东路六号
生产地址	福建省福州市闽侯县荆溪镇铁岭工业园一期九号东路六号
代理人	-----
代理人注册地址	-----
产品名称	隔离衣
型号/规格	连身式(160/XS、165/S、170/M、175/L、180/XL、185/2XL、190/3XL); 分身式(160/XS、165/S、170/M、175/L、180/XL、185/2XL、190/3XL); 反穿式(均码/ONE SIZE)
产品描述	通常采用非织造布为主要原料,经裁剪、缝纫制成。非无菌提供,一次性使用。
预期用途	用于医疗机构门诊、病房、检验室等做普通隔离。
备注	有效期 18 个月。
备案单位和日期	 福州市市场监督管理局 备案日期: 2020年05月06日
变更情况	2020年02月17日,该企业申请产品备案,备案的产品型号/规格为:连身式(150、160、165、170、175、180、185、190);分身式(150、160、165、170、175、180、185、190);2020年05月06日,该企业申请产品备案变更产品型号/规格为:连身式(160/XS、165/S、170/M、175/L、180/XL、185/2XL、190/3XL);分身式(160/XS、165/S、170/M、175/L、180/XL、185/2XL、190/3XL);反穿式(均码/ONE SIZE)

对外贸易经营者备案登记表

统一社会信用代码: 91350121793752244N

备案登记表编号: 03493846

进出口企业代码: _____

经营者中文名称	福建顺邦防护科技有限公司		
经营者英文名称	FUJIAN SAFETECH PROTECTION CO.,LTD.		
组织机构代码	_____	经营者类型 (由备案登记机关填写)	有限责任公司
住 所	闽侯县铁岭工业集中区		
经营场所 (中文)	闽侯县铁岭工业集中区		
经营场所 (英文)	Tieling Industrial Concentration Area, Minhou County		
联系电话	13799990797	联系传真	_____
邮政编码	350101	电子邮箱	linlinganny@163.com
工商登记注册日期	2006-10-8	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	刘玉林	有效证件号	350102196309100516
注册资金	陆仟陆佰肆拾万元		(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	已完成原产地申请人备案, 请到检验检疫机构/贸促会办理原产地证。
----	----------------------------------

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。



2020

04 年 月 日

出口方和进口方共同声明

Joint Declaration of the Exporter and the Importer

产品名称 (含规格、型号) Product Name (including specifications and model)	产品 数量 Product Quantity	中国质量标准名称或 国外质量标准名称 The Name of Quality Standards of China or the Foreign Country	进口国(地区) Importing Country/Region	生产厂商 Producer
医用一次性防护服 Disposable protective coverall S-3XL 非无菌型连身式 Non-sterile coverall	500000 件 500000pc s	GBT 19082-2009	英国 UK	福建顺邦防护 科技有限公司 Fujian Safetech Protection CO., Ltd

出口方和进口方确认上述产品符合 中国质量标准/ 国外质量标准 (请勾选), 且符合双方协议确定的产品质量标准。进口方保证协议确定的产品质量标准符合进口国(地区)对该产品的质量标准要求, 并确认接受上述产品的质量标准。

The exporter and the importer hereby confirm that the above products are compliant with the quality standards of China/ quality standards of foreign country (please tick the box) and the quality standards stipulated in the agreement between the parties. The importer shall guarantee the product quality standards stipulated by the agreement are compliant with the quality requirements of the importing country/region, and shall confirm it has accepted the quality standards of the above products.

进口方承诺严格依照协议不将所购防护服用于手术室, ICU 医用途, 并提示第三方不可用于手术室, ICU 医用途, 如因进口方或第三方使用、维护、保管不当造成损失的, 出口方、生产厂商不承担责任。

The importer shall commit to strictly abide by the agreement and not use the coveralls it purchases for surgical and ICU medical purposes and to warn any third party against using the coveralls for surgical and ICU medical purposes. The exporter or the producer is not liable for any losses caused by the inappropriate use, maintenance or keeping of the face masks by the importer or any third party.

本声明一式两份, 双方各执一份。

This declaration is made in duplicate, one original for each party.

特此声明



进口方 (签字)
Importer (Signature)
年 月 日
Day/Month/Year



Packing:

NON-STERILE

- 1PC per polybag
- 40pcs per carton
- Carton Measurement:55x37x25cm

<p>Disposable Isolation Gown</p>	<p>Model No.: PP+PE Disposable isolation gown Pieces: 40PCS Size: Free Size Carton Measurement: 55CMX37CMX25CM G.W.: KGS N.W.: KGS Carton No. : OF Company Name: Fujian Safetech Protection CO.,LTD Company Add: No.6 road east,Tieling industrial zone,Zone1 block 9 Jingxi town,Minhou county Fuzhou,Fujian province,P.R.China Tel.:+86-591-87807888 Fax.:+86-591-87826099 生产企业名称: 福建顺邦防护科技有限公司 生产地址: 福建省福州市闽侯县荆溪镇铁岭工业园一期九号东路六号 售后服务单位: 福建顺邦防护科技有限公司</p>



Safety Glasses Medical Use

Surgical headwear



Surgical gown

Protection coverall



Isolation gown



Shoe cover

Medical disposable nitrile gloves

Mask



[图片]

For more information, please visit:
www.spsafetech.com

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Call +0086-18605084833

E-mail: Paul_liu@spsafetech.com

Call +0086-15980223811

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SOUNDPOND INTERNATIONAL CO.,LTD
FUJIAN SAFETECH PROTECTION CO.,LTD
GREAT UNION GARMENT MFG.LIMITED

SAFETECH PROTECTION Disposable Protection
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