



Disposable Isolation Gown

Yellow PP+PE EN14126:2003-AC:2004 Type PB6-B
AAMI Level 1 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、	一次性隔离衣 Disposable Isolation Gown		
200	福建顺邦防护科技有限公司 Fujian Safetech Protection Co.,Ltd	91110115596057832U	欧盟CE

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

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

E-mail: infosafetech@spsafetech.com

Unified social credit code
统一社会信用代码

91350121793789244791

Business license 营业执照



(副 本) 副本编号: 1-1



扫描二维码
验证企业信用信息
“国家企业信用信息公示系统”
国家企业信用信息公示系统
网址: www.gsxt.gov.cn

名称: 福建赛邦防护科技有限公司
Company name: Fujian safetech protection co., ltd

类型: 有限责任公司(自然人投资或控股)
Type: limited liability company (private own)

法定代表人: 刘玉琳
Legal representative: Liu Yulin

经营范围

各种服装、针织服装、防护服、箱包、鞋帽、床上用品及其相关材料、纺织的生产、制造、安全用品设备及器材、防护用品和口罩制造、其他未列明的安全防护设备及器材、医疗器材及医药用品制造、医疗器械维修、非医用器械制造、其他器械制造、其他针织或钩针编织服装制造、其他家用纺织品、互联网零售、货物或技术进出口(依法须经批准的项目,经相关部门批准后方可开展经营活动)

注册资本 800.000000万人民币
The registered capital 8 Millions USD

成立日期 2006年10月08日
Date of establishment: 2006-Oct-08

营业期限 2006年10月08日 至 2056年10月07日
Term of operation 2006-Oct-08 to 2056-Oct-07

住所 闽侯县铁岭工业集中区

Address:
Tieling industrial concentration area, Minhou county

Business scope Production for all kinds of woven, knitted clothing, fire fighter clothing, bags and suitcases, hats, gloves and other related fabrics accessories; Wholesale and sale of gold ornaments; Manufacturing of medical protective masks; Manufacture of other medical equipment and apparatus not specified; Manufacturing of sanitary materials and medical supplies; Sales of medical devices; Nonwovens fabric manufacturing; Other woven clothing manufacturing; Manufacture of other knitted or crocheted garments; Wholesale of toilet appliances; Wholesale of groceries; Internet retail; Import and export of goods or technologies.



2020年2月12日

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,
闽侯县东岭路6号1号楼、2号楼、9号楼
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：

生产范围：二类I-IV类医护人员防护用品***
Fuzhou, Fujian province, P.R. China
Production scope:
class II 14-14 protective equipment for medical staff

企业负责人：刘玉林

Business owner: Liu Yulin

License issuing department: Drug administration of Fujian

住所：闽侯县铁岭工业集中区

Address: Tieling industrial concentration area,Minhou county

发证部门：

福建省药品监督管理局
福建省药品监督管理局

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





CERTIFICATE No. 20/2725/00/0161

PPE TYPE GOWN

REF: ISOLATION GOWN SPFH-GL001



AITEX, Notified Body No. 0161 for the application of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016, in which the essential health and safety requirements that Personal Protective Equipment (PPE) must comply with.

CERTIFIES The Company:

Fujian Safetech Protection Co., Ltd

No.6 road east, Tieling Industrial zone, Zone 1, Block 9, Jingxi town,

Minhou county, Fuzhou

Fujian province, China

As a manufacturer



CERTIFICATE No. 20/2725/00/0161

Has obtained EU TYPE EXAMINATION in compliance with what is stated in Regulation (EU) 2016/425 and in agreement with the applicable test procedures and technical specifications

Destined to the protection of entire body of the user, except feet, hands and head., according to the following standard/s:

- EN ISO 13688:2013 General Requirements.
- EN 14126:2003/AC:2004 to protection against biological agents: resistance to penetration of contaminated liquids under hydrostatic pressure (**Type PB6-B**).

The garment does **not** allow washing.

Having achieved the performance requirements specified in Technical Test Report No. **2020CN0288UE** and the PPE's Technical Documentation.

Description of the PPE:

- Coat made in yellow non-woven fabric with an exterior laminated.

The materials that form the PPE, are described in the technical report n° 2020CN0288UE.

The PPE is available with the following variants:

- It can be manufactured in blue color.

It shall be the manufacturer's responsibility to provide specific information of this certificate and the tested levels of protection.

The CAT. III PPE shall only be used in conjunction with one of the conformity assessment procedures according to module C2 or module D described in article 19 letter c) of the Regulation (EU) 2016/425.

Digitally Signed by: Sonia Figueres

Date: 19/06/2020 17:09:29

Location: Alcoy



Silvia Devesa Valencia
Laboratory Subdirector and Innovation

Date of issue of the Certificate: 19th of June 2020

Date of expiry: 19th of June 2025

EU DECLARATION OF CONFORMITY

Manufacturer: FUJIAN SAFETECH PROTECTION CO.,LTD

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

We, the manufacturer, declare under our sole responsibility that

The device(s) ISOLATION GOWN SPFH-GL001

is compliance with what is stated in Regulation (EU) 2016/425 and in agreement with the applicable test procedures and technical specifications.

Applied harmonized Standards, national Standards or other Normative documents ENISO13688:2013
EN14126:2003/AC:2004


The garment does not allow washing.

Having achieved the performance requirements specified in Technical Test Report No. 2020CN0287 and the PPE's Technical Documentation.

Notified Body (Name & Number) AITEX, Notified Body No. 0161

Certificate number

Signed on: June 16, 2020 Place: Fuzhou, Fujian, China

Signature (on behalf of the manufacturer) 
FUJIAN SAFETECH PROTECTION CO.,LTD
Authorized Signature



Name of authorized signatory: Liu Yulin
Position held in the company: General Manager

Yellow PP+PE EN14126:2003-AC:2004 Type PB6-B Disposable Isolation Gown



Isolation gown

Product description

- 50 g spun bonded polypropylene disposable gown designed to
- Provide superior protection against cross contamination
- High level fluid repellence
- Knitted cuffs, waist ties and Velcro neck closure

SIZE INFORMATION

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

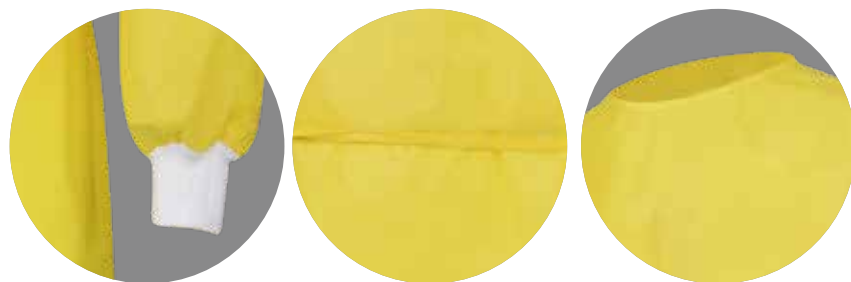
Product	Isolation gown
Style NO	SPFH-GL001
Material	Fabric: Polypropylene (PP) + polyethylene (PE)
	Weight: 50gsm
Color	yellow Blue
Sizing	An appropriate size should be selected

EN 14126



TYPE 6B

EN 13034



Fabric and structure

- Anti-wrinkle**
- Anti-static**
- Against liquid splashes**
- Does not fade**

Impervious Isolation Gowns — Coated Polypropylene

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



EVALUATION OF THE CONFORMITY

2020CN0288UE

APPLICATION DATE
13/05/2020

APPLICANT

FUJIAN SAFETECH PROTECTION CO., LTD
No.6 road east, Tieling Industrial zone,
Zone 1, Block 9, Jingxi town,
Minhou county, Fuzhou,
Fujian province,
China

IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES

ISOLATION GOWN SPFH-GL001

TESTS CARRIED OUT

- OBSERVATIONS
- DESCRIPTION OF SAMPLE
- ESSENTIAL REQUIREMENTS
- EVALUATION FOR EU TYPE CERTIFICATION
- CONCLUSION OF THE CONFORMITY EVALUATION

2020CN0288UE



DESCRIPTION OF SAMPLES

ISOLATION GOWN SPFH-GL001

Coat made in yellow non-woven fabric with an exterior laminated.



The PPE is available with the following variants:

It can be manufactured in blue color.





SPFH-GL001

USER MANUAL

CE 0161
PPE CAT. III



EN ISO 13688:2013



AET-SPFH-GL001 DISPOSABLE ISOLATION GOWN

Description
Disposable isolation gown is made of non-woven polypropylene and polyethylene film. The isolation gowning process is as follows:
Main material: 100% Polypropylene and polyethylene film.
Color: White.
Material: Non-woven, Polyamide (Nylon).
Classification: Disposable.
Length: 120cm.
Chest: 80cm.
Sleeve length: 51cm.
Cuff: Elastic.
Cuff type: Elastic.
EN 14126:2004
EN 14126 is classified as Category III Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425. The product meets the requirements of the European Standards EN 14126:2004 General Requirements and EN 14126:2004 Protective Clothing - Polypropylene requirements and tests methods for protective clothing against infective agents (PBAB).
EN 14126:2004: Complex design PPE that protect against the risks that may cause very serious health hazards such as viral or transmissible spongiform encephalitis.
EN 14126:2004: Fully protective for identification and isolation of contagious conformity according to Module C2 or, class, Type Limited Use 1, SUBTYPE ALCOY (ALCOY), Spain. Approved Body No. 0181.

Performance
Test performance quoted below is based on laboratory data and may not reflect the actual situation of protection in the workplace due to other factors influencing the performance such as operation, mechanical wear, etc.

Results of protection in compliance with EN 14126:2004:2004

Property	Test Method	Results	EN Class*
Minimum Resistance	EN ISO 12947-2	> 2200 gforce	3 of 5
Flex Creasing Resistance	EN ISO 1854 Method B	> 2000 cycles	3 of 5
Reproducible Tear Resistance	EN ISO 6075-4	> 20 N	3 of 5
Puncture Resistance	EN 883	> 5 N	1 of 5
Force Integrity	EN ISO 13884-1	> 40N	2 of 5
Resistance to Flame	EN 12274-4 Method B	Pass	1 of 2
Resistance to penetration by synthetic blood under hydrostatic pressure	ISO 18604 (Procedure C)	> 33 kPa	3 of 5
Resistance to penetration by blood borne pathogen using Ph.D.18	ISO 18604 (Procedure C)	30 MPa	3 of 5
Resistance to Wet Bacterial Penetration**	EN ISO 22610	15-1000	2 of 5
Steam Sterility	EN ISO 13885-2	> 50 N	2 of 5

Performance requirements in compliance with the EN ISO 13688:2013

Property	EN ISO 3071	Pass
pH Value	EN ISO 3071	Pass
AZO Dye	EN 14562-1	Pass

* Requirements according to the Standard EN 14353:2018.
** Information from user's use review.

- User Guide**
- Donning Instructions**
1. Always remember hand hygiene! Clean your hands before taking the isolation gown on.
 2. Start by pulling the individual gown from the bag.
 3. Inspect the gown prior to donning for any rips, or holes. If there is a hole or tear discard the gown and repeat the donning process.
 4. Take hold of the gown from the folded edge and allow the remainder of the gown to unfold. With both hands holding either side of the neck opening evenly, snap the gown down to release the rest of the gown. Gown is now ready to be donned.
 5. Place arms into the sleeves and hands into the thumb loop cuffs if they apply to your gown.
 6. Pull the gown overhead.
 7. Pull the side tabs to the back of the gown and tie at the rear of the waist.

- Doffing Instructions**
1. Leaving your medical gloves on, start by crossing your arms across on the shoulders and pull the gown away from the body to break the neck closure.
 2. Move down to your waist grasp the gown, and pull away from the body to break waist closure.
 3. Roll the gown down the body inside out into a ball with your medical gloves to ensure fluids and contaminants are contained.
 4. Discard of the gown in an appropriate receptacle. Some users may require special disposal depending on your local facilities rules and applicable regulations.

Packaging Storage & Transportation

Store in a clean room with a relative humidity of not more than 80% and well-ventilated environment with no corrosive gases.

The transportation process should be performed in accordance with the contract's provisions. Avoid heavy pressure deformation, direct sunlight, hard objects scratching and tear or stain or liquid washing.

Preferably stored in original packaging under dry conditions.

When stored as recommended, the product will not suffer any chemical properties for up to the year from the date of manufacture. Service life cannot be specified and depends on application and responsibility of user to ascertain suitability of the glove for its intended use.

- Use Limitations and Disposal:**
- Corrosive
 - For use
 - The use
 - Disposal
 - Hand
 - The use

产品合格证
Product Certification

检验合格，准予出厂。
The product passed the inspection and is hereby approved.

产品名称	规格型号
产品名称	Disposable Isolation Gown
产品型号	SPFH-GL001
产品规格	SPFH-GL001
产品数量	1000
生产日期	2024.11.15
生产地址	福建省晋江市
检验员	李强
检验日期	2024.11.15
检验项目	外观、尺寸、拉力、透气性
检验结果	合格
检验依据	YY0596.2-2004
检验标准	14.562
产品标准	YY0596.2-2004
产品编号	0000000000
生产地址	福建省晋江市
地址	No. 8 road east, Taling industrial zone, Zone 1, Nishi 3, Jingshi town, Maoyao county, Fujian, Fujian province P.R. China

福建晋江安泰防护用品有限公司
MADE IN CHINA

Soundpond
Technical performance

FUJIAN S...
N

TD
E (1)
NTY
QUAN
7888
COM



Details

SAFETECH PROTECTION • DISPOSABLE ISOLATION GOWN



Test Report SL52025245289101TX Date: April 28, 2020 Page 1 of 3
FUJIAN SAFETECH PROTECTION CO.LTD
NO.6 ROAD EAST, TIELING INDUSTRIAL ZONE(1), JINGXI TOWN, MINHOU COUNTY, FUZHOU 350101,
FUJIAN

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Isolation gown
Style No. : SPFH-GL001
Composition : (A) 100% polypropylene
Sample Color : (A) yellow
Manufacturer : FUJIAN SAFETECH PROTECTION CO.LTD
Sample Receiving Date : Apr 20, 2020
Testing Period : Apr 20, 2020 - Apr 28, 2020
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed : Selected test(s) as requested by applicant

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

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Test Report
Test Result

SL52025245289101TX

Date: April 28, 2020

Page 2 of 3

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
(AATCC 42-2017)

As received

Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	0.0	0.0	0.1	0.0	0.1
Area B (Critical zone-sleeve)	0.0	0.0	0.1	0.1	0.1
Area C (Critical zone-back)	0.0	0.0	0.0	0.0	0.0
Seam between areas A&B	0.0	0.1	0.1	0.0	0.1
Seam between areas A&C	0.1	0.0	0.1	0.1	0.0
Seam between areas B&C	0.2	0.1	0.2	0.2	0.1

Remark:

- Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5grams(g)
- Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)
- 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

(AATCC 127-2018; Hydrostatic Head; Rate of increase of water pressure: 60mbar/min; temp. of distilled water: 21 ° C, fabric face side of water)

As received

Water Column (cmH ₂ O)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	15.6	13.8	14.4	14.9	15.7
Area B (Critical zone-sleeve)	14.1	13.7	13.1	11.7	14.2
Area C (Critical zone-back)	>20.0	>20.0	>20.0	>20.0	>20.0
Seam between areas A&B	11.5	14.9	12.8	10.8	12.0
Seam between areas A&C	13.4	14.8	13.0	11.8	13.8
Seam between areas B&C	10.5	14.5	13.1	12.1	13.7

Remark:

- Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH₂O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH₂O



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Barrier performance of each component and final classification commended.

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH ₂ O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (critical zone-front)	0.1	13.8	/	Level 1	Level 1
Area B (critical zone-sleeve)	0.1	11.7	/	Level 1	
Area C (Critical zone-back)	0.0	>20.0	/	Level 2	
Seam between areas A&B	0.1	10.8	/	Level 1	
Seam between areas A&C	0.1	11.8	/	Level 1	
Seam between areas B&C	0.2	10.5	/	Level 1	

Remark:

- 1) 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.
- 2) Level 1: Impact Penetration Test-AATCC 42: <4.5g;
- 3) Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH₂O;
- 4) Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH₂O;
- 5) Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.

Sample Photo



Face

Back

End of Report



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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园一期九号东路六号			
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			
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	
	医用隔离鞋套	闽榕械备20200050号	2020年5月6号	


备案部门： 福州市市场监督管理局

备案日期： 2020 年 05 月 06 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
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。
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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 月 日

Packing:

NON-STERILE

- 1PC per polybag
- 40pcs per carton
- Carton Measurement: 55x37x23cm



<p>Disposable Isolation Gown</p>	<p>Model No.: PP+PE Disposable isolation gown Pieces: 40PCS Size: Free Size Carton Measurement: 55CMX37CMX23CM 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>

