

# Certificate of Compliance

No. 0H200315.JSGUD95



Certificate's  
Holder:

Jiangsu Sunshine Group Co., Ltd.  
Xinqiao Town, Jiangyin City, Wuxi City, Jiangsu,  
P.R.China

Certification ECM  
Mark:



Product:  
Model(s):

Medical Disposable Protective Clothing  
160, 165, 170, 175, 180, 185

Verification to:

Standard:  
EN 14605:2005+A1:2009,  
EN 14126:2003+AC:2004, EN ISO 13688:2013,  
EN 340:2003

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

**Issuance date: 15 March 2020**

**Expiry date: 14 March 2025**

Reviewer  
Technical expert  
Amanda Payne



Approver  
ECM Service Director  
Luca Bedonni



**Ente Certificazione Macchine Srl**

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**Fiscal Year 2020**  
**FDA REGISTRATION CERTIFICATE**

Certificate No.: JF-FDA-0321-0093

**Certificate Holder:**

**JIANGSU SUNSHINE GROUP CO., LTD.**

Xinqiao Town, Jiangyin City,

Wuxi, Jiangsu, 214426, CHINA

has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer ) and Device Listing with the US Food & Drug Administration.

**Registration Number: N**

**Owner/Operator Number: 10063463**

Device Listing:

Device#	Product Codes	Device Name
D376513	OEA	Non-surgical isolation gown (Disposable Protective Clothing)

**Registration Expiration Date: 2020-12-31**

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuant to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

**J&F TECHNOLOGY SERVICES LLC.**

**2424 Morris Ave 818 Union**

**NEW JERSEY 07083**

**United States**







## DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

**Manufacturer:**

Company name: Jiangsu sunshine group co.,ltd  
Address: No.18, Taoxin Road, Xinqiao Town,  
Jiangyin city, Jiangsu Province, P.R. China  
Tel: +86 0510-86121888

**Whose Authorized Representative:**

Name: Lotus NL B.V.  
Address: Koningin Julianaplein 10,1e  
Verd, 2595AA, The Hague, Netherlands.  
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	Model	Basic UDI-DI
Medical disposable protective clothing (non sterile)	Gowns	I, Rule I (Annex VIII of MDR)	Coverall	

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

**Conformity Assessment Route:** Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

**Applicable Standards:**

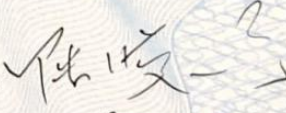
ISO 13485:2016  
ENISO 10993-5: 2009  
EN 1041:2008

ISO 14971:2019  
ENISO 10993-10: 2013  
EN 15223-1:2016

ISO 10993-1: 2018  
EN 14126-2003

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

**Name of authorized signatory:** Xiaoming Lu

**Signature:** 

**Position held in the company:** General Manager

**Date:** 13-04-2020

**Place:** Jiangsu, China

Jiangsu sunshine group co.,ltd

**Seal/Stamp:** 



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 332463 XZ PTY LTD - Gown, isolation, single use

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** XZ PTY LTD  
**Postal Address** 518/4 Seven Street, Epping, NSW, 2121  
Australia  
**ARTG Start Date** 25/03/2020  
**Product category** Medical Device Class 1  
**Status** Active  
**Approval area** Medical Devices

**Conditions**

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

**Manufacturers**

**Name**

Jiangsu Sunshine Group Co Ltd

**Address**

Xinqiao Town Jiangyin City  
Wuxi, Jiangsu, 214426  
China

**Products**

**1. Gown, isolation, single use**

**Product Type** Single Device Product **Effective date** 25/03/2020

**GMDN**

35492 Gown, isolation, single use

**Intended purpose**

The medical disposable protective clothing (below called protective clothing for short) is made of spun-bonded non-woven fabric and adopts PE breathable film composite technology. The production environment has reached the environmental standard of 100,000 class clean workshop. The whole production process meets the technical requirements of the medical protective clothing, also meet the requirements of GB19082-2009 (medical disposable protective clothing technical requirements), it has good anti-static performance, hydro-static pressure, filtering efficiency, anti-synthetic blood penetration, breaking strength, breaking elongation and other indicators can meet the standard requirements, it can effectively resist dust and water. The protective clothing can be used for the medical staff in the common ward of the medical institution, effectively preventing the virus from the patient spreading to the medical staff with the air or the liquid.

The technical requirements are applicable to the protective clothing that provides barrier and protection for the medical staff to contact the potentially infectious patients' blood, body fluids, secretions, airborne particles and etc. The protective clothing should be dry, clean and free from mildew. No adhesion, cracks, holes and other defects are allowed on the surface, the connecting parts of protective clothing can be processed by stitching, bonding or heat bonding. The needle hole of the stitching seam should be sealed, and the stitch spacing should be 8-14 stitches per 3cm. The stitching should be even and straight, without jumping needle. The parts after bonding or heat bonding should be flat, sealed without bubbles, the zipper of the protective suit with zipper shall not be exposed, and the zipper shall be self-locking. The protective clothing is composed of hooded jacket and trousers, which is one-piece structure, should be reasonable, easy to wear and take off, and the binding part should be close. The elastic retainer is used for cuff, ankle, cap face and waist, drawstring retainer or buckle is also used for cap face and waist. The size of protective clothing is divided into 160, 165, 170, 175, 180 and 185. The hydro-static pressure at key parts of the protective clothing shall be no less than 1.67kPa(17cmH<sub>2</sub>O). The moisture permeability of protective clothing should be no less than 2500g/(m<sup>2</sup>·d), resistance to synthetic blood penetration. The water level on the outside of the protective clothing shall not be lower than grade 3. The breaking strength of materials in key parts of protective clothing shall be no less than 45N.

The filtration efficiency of non-oil particles in key parts of protective clothing and joints should be no less than 70%. The electric quantity of protective clothing shall not be greater than 0.6μC/piece. The protective clothing should meet the requirements of the microbial indications in GB15979. Received certificate of compliance ECM Mark: European Conformity. Verification to Standard: EN 14605:2005+A1:2009, EN14126:2003+AC:2004, EN ISO 13688:2013, EN 340:2003. Related to CE Directive(s) R2016/425. Received FDA registration certificate (JF-FDA-0321-0093).

**Specific Conditions**

# 中华人民共和国医疗器械注册证

注册证编号：苏械注准应急 20202140007

注册人名称	江苏阳光集团有限公司
注册人住所	江苏省江阴市新桥镇陶新路 18 号
生产地址	江苏省江阴市新桥镇陶新路 18 号
代理人名称	不适用
代理人住所	不适用
产品名称	医用一次性防护服
型号、规格	160、165、170、175、180、185、190、195
结构及组成	本产品由连帽上衣和裤子连体结构组成。材质为无纺布+PU 膜，产品为非无菌提供。
适用范围	适用于接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用。
附 件	产品技术要求
其他内容	
备 注	

审批部门：江苏省药品监督管理局

批准日期：2020 年 04 月 03 日

有效期至：2021 年 04 月 02 日





## EC-Declaration of Conformity

Manufacturer: JIANGSU SUNSHINE GROUP CO., LTD  
Taoxin Road 18, Xinqiao Town, Jiangyin City, Jiangsu

Province  
Device Name and  
Variants: Medical Disposable Protective Clothing

Model(s): 160,165,170,175,180,185  
Standard: EN 14605:2005+A1:2009  
EN 14126:2003+AC:2004, EN ISO 13688:2013,  
EN 340:2003

Conformity  
Assessment Route: CE Directive(s) R 2016/425  
(Personal Protective Equipment)

We hereby to certify that under our sole responsibility the above mentioned product conforms to the provisions of the following EC Council Directives and Standards. All Supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

General applicable directives:

Personal Protective Equipment: Related to (EU)2016/425(Personal Protective Equipment) .

Website: <http://www.china-sunshine.com/m/index.php/service/info/others?en=en>

Start of CE Marking:  
Place, Date of Issue:

Not Yet  
Jiangyin, 2020-03-07

Signature/Date:  
General Manager:

Mr. Xiaoming Lu(陆晓明先生)







Jiangsu Guojian Testing Technology Co.,Ltd

# Test Report

[2020] WSZ FHL NO.0842

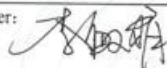
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Product name	Medical disposable protective clothing (Non-sterile)	Specification	160
		Brand	—
Applicant/Add /Tel	Jiang Su Sunshine Group Co., Ltd /Xinqiao, Jiangyin/ 13815131713		
Manufacturer/Add/Tel	—/—/—		
Sample grade	—	Sample number	GW0842-2020
Sample quantity	6	Receiving date of sample	2020.02.24
Test type	Entrusted inspection	Article number/Batch number/Style number	9N020—F00010A
Test date	2020/02/25~2020/03/03	Test site	Testing room
Sample state	Meet the requirements		
Test standard(s)	GB 19082-2009 《Technical requirements for disposable protective clothing for medical use》		
Test items	Water permeability、Moisture permeability、Synthetic blood penetration resistance、Surface moisture resistance、Breaking strength、Breaking elongation、Filtering efficiency、Antistatic、Appearance、Model Specification (One-piece pose)、Microorganism、Electrostatic attenuation performance		
Test conclusion	<p>The sample upon examination, the projects meet the requirements of the GB 19082-2009 standard, the specific test results see page 2-3.</p> 		
Note	<p>The sample information is provided by Applicant. This report is only responsible for samples received.</p> 		

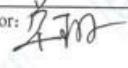
Approver:



Reviewer:



Main surveyor:



检测专用章



# Test Result

[2020] WSZ FHL NO.0842

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Number	Test item		Unit	Technical requirements	Test Result		Single Item decision
1	Water permeability		kPa	$\geq 1.67$	30.8		Qualified
2	Moisture permeability		$\text{g}/(\text{m}^2 \cdot \text{d})$	$\geq 2500$	6870		Qualified
3	Synthetic blood penetration resistance		—	$\geq \text{Level } 2$	Level 6		Qualified
4	Surface moisture resistance		—	$\geq \text{Level } 3$	1#	Level 4	Qualified
					2#	Level 4	
					3#	Level 4	
5	Breaking strength	lengthwise	N	$\geq 45$	98		Qualified
		the width			45		
6	Breaking elongation	lengthwise	—	$\geq 15\%$	35.5%		Qualified
		the width			108%		
7	Filter efficiency	Key position material	—	$\geq 70\%$	99.4%		Qualified
					99.7%		
					99.4%		
		seam	—	$\geq 70\%$	99.2%		
					99.4%		
					99.2%		
8	Antistatic		$\mu\text{C}/\text{PC}$	$\leq 0.6$	0.19		Qualified
9	Microorganism	Bacterial colony count	cfu/g	$\leq 200$	$1.1 \times 10^2$		Qualified
		Escherichia coli	—	Negative	Not detected		
		Pseudomonas aeruginosa	—	Negative	Not detected		
		Staphylococcus aureus	—	Negative	Not detected		
		Hemolytic streptococcus	—	Negative	Not detected		
		Fungal colony count	cfu/g	$\leq 100$	24		

## Test Result

[2020] WSZ FHL NO.0842

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Number	Test item	Unit	Technical requirements	Test Result	Single Item decision							
10	Electrostatic attenuation performance	s	$\leq 0.5$	0.2	Qualified							
				0.2								
				0.3								
				0.2								
				0.3								
11	Appearance	—	Protective clothing should be dry, clean, mildew free, the surface is not allowed to adhesion, cracks, holes and other defects.The joint parts of protective clothing can be stitched, bonded or heat-bonded.The holes of the stitch shall be sealed, and the stitch spacing shall be 8-14 stitches per 3cm.After processing, such as bonding or heat bonding, to be flat, sealed, no bubbles.Zipper fitted protective clothing zipper can not leak, pull head should be able to self - lock.	The stitch spacing is 12 stitches per 3cm. Meet the requirements	Qualified							
12	Model Specification (One-piece pose)	cm	Model	Model: 160			Qualified					
			Body length	average	Deviation							
			160	165	120	84		18	24	Body length	163.6	-1.4
			165	169	125	86		18	24	Bust circumference	120.3	0.3
			170	173	130	90		18	24	Sleeve length	84.2	0.2
			175	178	135	93		18	24	Cuff	18.1	0.1
			180	181	140	96		18	24	INSTEP	24.1	0.1
			185	188	145	99		18	24			
			Deviation	$\pm 2$	$\pm 2$	$\pm 2$		$\pm 2$	$\pm 2$			
			Note									

The End