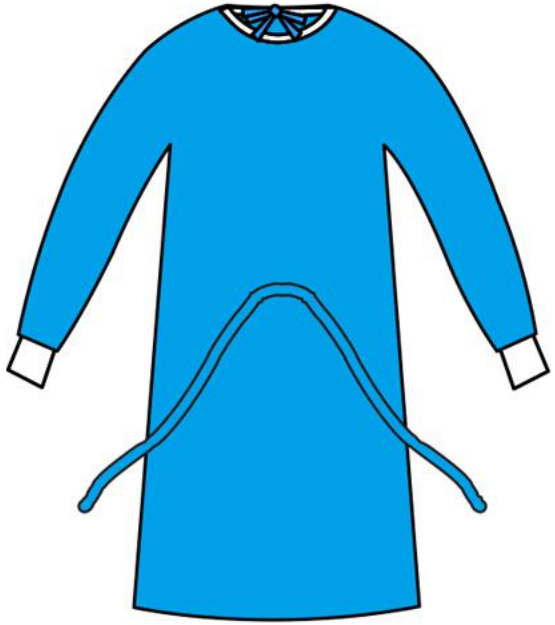
Size	Daily Q'ty	Price
XL	40,000PCS	CNY/PC
L		CNY/PC
M		CNY/PC

Mesarment:57x33x30cm
Manner of packing:1pcs/bag
60bag/carton

Standard Surgical Gown

Certificate
> CE
> FDA
> ISO 13485
> EN13795



Surgical Gown Size				Unit:cm
Size	**M**	**L**	**XL**	**Tolerance**
A	115	127	135	±2

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 053056 0019 Rev. 01

Holder of Certificate: **Kunshan Jiehong Nonwoven Product Co., Ltd.**
895 Xinle Rd., Dianshanhu Town
215345 Kunshan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Non-woven devices intended for Operations and Isolation Facilities(Caps, Masks, Shoe Covers, Isolation Gowns, Surgical Gowns, Back Table Covers, Stockinetes, Wraps, Leggings, Surgical Drapes), Surgical Towels, Instrument Towels, Protective Cover, Surgical Set**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1903122

Valid from: 2019-10-09
Valid until: 2022-09-30

Date, 2019-10-09

Stefan Preiß
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 053056 0019 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Kunshan Jiehong Nonwoven Product Co., Ltd.
895 Xinle Rd., Dianshanhu Town, 215345 Kunshan, PEOPLE'S REPUBLIC OF CHINA

Kunshan Jiehong Nonwoven Product Co., Ltd.
66 Qiansheng Rd., Dianshanhu Town, 215345 Kunshan, PEOPLE'S REPUBLIC OF CHINA

A4 / 07.17

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 11 53056 020

Manufacturer: **Kunshan Jiehong Nonwoven Product Co., Ltd.**
895 Xinle Rd., Dianshanhu Town
215345 Kunshan
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Surgical Gowns, Surgical Drapes, Sterile Instrumental Cover, Sterile Protective Cover**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH17031EXT01

Valid from: 2018-01-10
Valid until: 2023-01-09

Date, 2018-01-05

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 11 53056 020

Facility(ies):

Kunshan Jiehong Nonwoven Product Co., Ltd.
895 Xinle Rd., Dianshanhu Town, 215345 Kunshan,
PEOPLE'S REPUBLIC OF CHINA

Kunshan Jiehong Nonwoven Product Co., Ltd.
66 Qiansheng Rd., Dianshanhu Town, 215345
Kunshan, PEOPLE'S REPUBLIC OF CHINA

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A1 / 04.11

对外贸易经营者备案登记表

备案登记表编号：03703885　　统一社会信用代码：91440300356440437Q
进出口企业代码：

经营者中文名称	深圳市众创美力生物科技有限公司		
经营者英文名称	SHENZHEN BEAUTY SHARE BIOTEC 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	深圳市前海深港合作区前湾一路1号A栋201室（入驻深圳市前海商务秘书有限公司）		
经营场所（中文）	深圳市前海深港合作区前海一路1号A栋		
经营场所（英文）	Room 201, building A, No. 1th, Shenzhen, Shenzhen cooperation zone, Qian Hai		
联系电话	0755-22671051	联系传真	0755-22671051
邮政编码	518000	电子邮箱	393844171@qq.com
工商登记注册日期	2015-9-7	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	李阳	有效证件号	36232119901108002x
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 04 月 26 日

QG07

中华人民共和国海关
报关单位注册登记证书

海关注册编码：4403149328

组织机构代码：356440437

企业名称：深圳市众创美力生物科技有限公司

企业住所：深圳市前海深港合作区前湾一路1号A栋201室（入驻深圳市前海商务秘书有限公司）

企业经营类别：进出口货物收发货人

注册登记日期：2018年8月23日

法定代表人：李阳

有效期：长期

注册海关：深关现场

核发日期：2018年8月23日

重要提示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

中华人民共和国海关总署监制

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 202015904 号

企业名称	深圳市众创美力生物科技有限公司
法定代表人	李阳
企业负责人	李阳
经营方式	批零兼营
住　　所	深圳市前海深港合作区前湾一路 1 号 A 栋 201 室（入驻深圳市前海商务秘书有限公司）
经营场所	深圳市前海深港合作区前湾一路 1 号 A 栋 201 室（入驻深圳市前海商务秘书有限公司）
库房地址	深圳市前海深港合作区前湾一路 1 号 A 栋 201 室（入驻深圳市前海商务秘书有限公司）
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（体外诊断试剂除外），6840（诊断试剂需低温冷藏运输贮存），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）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，6840 体外诊断试剂，6840 体外诊断试剂（不需低温冷藏运输贮存），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 02 月 28 日

Test Report No.: 721627723-4
Report Date: 13 June 2017

ORIGINAL

SUBJECT	**Physical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**KUNSHAN JIEHONG NONWOVEN PRODUCT CO.,LTD**
CLIENT ADDRESS	895,Xinle Road,the Economic and Technical development zone of DianshanHu Town,Kunshan City
TEST PERIOD	22-Aug-2016~30-Aug-2016

Prepared By

(Gao Ju)
Report Drafter

Authorized By

(Shen Li)
Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

Impact penetration of water resistance

1. **Purpose**

   The purpose of the test was to determine the resistance of fabrics to the penetration of water by impact, and thus can be used to predict the probable resistance of fabrics to rain penetration.

2. **Sample description was given by the client**

   Surgical Gown M1230-100

3. **References**

   AATCC 42-2013 Type II

4. **Apparatus**

   Impact penetration tester

5. **Test specimen**

   5.1 As requested by the client,total 13 samples to take specimens from junction of belt,front sheet and seam of sleeve for every sample.
   5.2 Cut approximately 178mm*330mm test specimen with the length wise in the long direction.
   5.3 The specimens and the blotting paper should be conditioned in an atmosphere of 65±5% RH and 20±2°C for at least 4h before testing.

6. **Procedure**

   6.1 One end of the specimen clamped under the spring clamp at the top of the inclined stand. Another clamp is clamped at the free end of the free end of the test specimen.
   6.2 A standard blotter paper is weighed to nearest 0.1 and inserted beneath the test specimen.
   6.3 A 500±10mL volume of distilled deionized water at 27±1°C is poured into a funnel of the tested and allowed to spray onto the test specimen.
   6.4 Upon completion of the spraying period, the test specimen is carefully lifted, the blotter beneath removed, and then quickly reweighed to the nearest 0.1g.

7. **Calculation**

   As requested by the client,calculation the individual result of each specimen.

Chemical/Microbiology Laboratory:
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Phone : +86 (21) 6037 6375
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

8. Test results

Test Items*		Test Results			Test Methods
		Junction of belt	Front sheet	Seam of sleeve	
Water Resistance Impact Penetration Test (g)	1	0	0	0	AATCC 42-2013 Type II
	2	0.1	0	0	
	3	0	0.1	0	
	4	0.1	0.1	0	
	5	0.1	0.1	0	
	6	0	0	0	
	7	0	0	0	
	8	0.1	0	0	
	9	0	0.1	0	
	10	0	0	0	
	11	0.1	0	0	
	12	0	0	0	
	13	0	0.1	0	

Note:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
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Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 , P.R.China

CERTIFICATE OF REGISTRATION

This certifies that:

KunShan Jiehong Nonwoven Product Co., Ltd
895 Xinle Road, Dianshan' hu Town,
Kunshan, Jiangsu
China 215345

is registered with the U.S. Food and Drug Administration pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations, such registration having been verified as currently effective on, and as of the date hereof .

Establishment Registration:	**3006437555**
510(K) number:	**K070431(gown)**

医疗器械产品技术要求

医疗器械产品技术要求编号：苏苏械备 20200052 号

隔离衣

1. 产品型号/规格及其划分说明

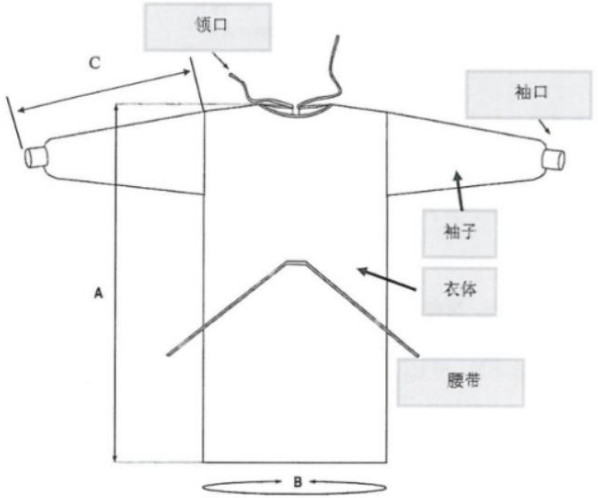
1.1 分类和组成

隔离衣由无纺布缝制的带固定带的衣体和袖子组成。

1.2 规格型号

隔离衣的按外形分为前扣式和后扣式两种型式，后扣式型式的规格按尺寸为大号、中号和小号三种规格，前扣式型式的规格按尺寸大小分为 M、L、XL、XXL 四种规格。

1.3 后扣式和前扣式隔离衣的示意图见图 1、图 2。



A—衣长　　B—胸围　　C—袖长

图 1　后扣式隔离衣的示意图

表 1　隔离衣的基本尺寸

单位为厘米

型式规格		衣长 A	胸围 B	袖长 C
后扣式	大号	140±20	160±30	54±10
	中号	120±20	130±30	50±10
	小号	100±20	110±30	48±10
前扣式	M	110±20	60±10	50±10
	L	112±20	63±10	50±10
	XL	116±20	66±10	50±10
	XXL	118±20	70±10	54±10

2.4　液体阻隔功能

隔离衣应不透水。

2.5 断裂强力

隔离衣胸部材料的断裂强力应不小于 15N。

3. 检验方法

3.1 外观

3.1.1 目视检查，针距使用通用量具进行测量，应符合 2.1.1 的要求。

3.1.2 对每件隔离衣样品的拉锁进行拉合操作 5 次，测定 3 件，均应符合 2.1.2 的要求。

3.1.3 目视检查，应符合 2.1.3 的要求。

3.2 结构

目视检查，应符合 2.2 的要求。

3.3 号型规格

使用通用量具，对每种号型的隔离衣样品进行测量，测定 3 件，其规格均应符合 2.3 的要求。

3.4 液体阻隔功能

将隔离衣展开在平台上，在隔离衣的前胸部位喷洒水，观察 30s，结果应符合 2.4 的要求。

3.5 断裂强力

隔离衣胸部材料按照 GB/T3923.1-1997 规定的条样法进行试验，结果应符合 2.5 的要求。

隔离衣

产品使用说明书

【产品名称】隔离衣
【生产备案编号】苏苏食药监械生产备 20196001 号
【产品备案编号】苏苏械备 20200052 号
【产品技术要求编号】苏苏械备 20200052 号
【结构组成】
隔离衣按外形分为前扣式、后扣式和连体式三种形式。前扣式和后扣式隔离衣由无纺布缝制的带固定带的衣体和袖子组成；连体式隔离衣由衣体、袖子和帽子组成。
【型式规格】
前扣式型式的规格按尺寸大小分为 M、L、XL、XXL 四种；后扣式型式的规格按尺寸大小分为大号、中号、小号三种；连体式型式的规格按尺寸大小分为大号、中号、小号三种。
【适用范围】
本产品用于医疗机构门诊、病房、检验室等作普通隔离。
【使用说明】
一、沿开口处打开包装，取出衣服；
二、穿戴将应遵循以下顺序：打开衣服将手臂分别伸入衣服袖子内，先将领口系扣固定住，再将腰带系扣固定住；
三、脱除将应遵循以下顺序：先解开腰部固定系扣，再解开领口固定系扣，最后脱掉衣服。
【注意事项】
1. 本产品为疫情应急产品。
2. 本产品以非灭菌形式提供。
3. 本品为一次性使用产品，严禁重复使用。
【贮存】
本产品应贮存在通风、干燥的室内，不得与有毒、有害或有腐蚀性的物质混存。
【禁忌症】无。
【符号说明】

一次性使用

防止热源

保持干燥

Disposable Surgical Gown

1. Description

Disposable Surgical Gowns are critical items of protective clothing suitable for Operation Room, medical clinics, hospital ward, inspection rooms, laboratories, ICU and CDC sites for important isolation of virus damage.

At Joinkona Medical Company, there is a wide selection of disposable surgical gowns made of SMMS that will certainly serve to protect medical staffs in situations where there are exposure concerns.

2. Advantages to wearing disposable Surgical Gown

Raw Material: Weight: 45g/M2 PP Non-woven Fabrics.
SMMS Performance: Fluid Proof and Anti-Static or Fluid Proof and Anti-Static and Anti-Alcohol and Anti-Blood(AS&AR)

In the healthcare profession, disposable surgical gown play a crucial role in asepsis by reducing the transfer of bacteria from the skin of the medical staff to the air and protect medical staff in operation room. Besides, It will also protect staff members from blood, urine, saline, or other chemicals and bodily fluids during surgical procedures.

Comfortable, Lightweight and Breathable
They are breathable allowing the wearer to be insulated and not overheat.

3. Specifications and Features
Style One piece of Disposable Surgical Gown
Features ✡ Single use ✡ Secure protection (ultrasonic technology)
✡ Anti-fluid, Anti-alcohol, Anti-blood , Antistatic ✡ Durable ✡ Comfortable, Lightweight and Breathdfcle ✡ Tear-resistant ✡ Flame retardant