

## MEDICAL COVERALL SUIT





#### ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.

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## 浙江华福医用器材有限公司

地址:浙江省平湖市经济开发区新兴一路688号 电话: 0573-85098390 传真: 0573-85155298 邮箱: sales@huafuzj.com 网址: www.huafuzj.cn

## STANDARD GB 19082-2009 医用隔离衣

## SINCE **1983** 华夏福音 造福人类





Quality is heavier than Mount Tai, Innovation is the soul of development of enterprise.

# 华福医械简介

浙江华福医用器材有限公司创始于1983年, 致力于医疗器械产品的研发、生产和海内外销售。 公司2003年通过ISO9001、ISO13485 质量管理体系认证,目前拥有TUV(南德意志) ISO13485质量管理体系认证和一系列CE产品 认证,产品销往全球30多个国家和地区。

华福主要生产医用防护产品以及医用耗材, 主要产品:医用防护服,隔离衣,医用口罩, KN95口罩,输液器,注射器等,生产规模处于 国内领先地位。公司自成立起一直坚持创新之路, 公司已累计申请专利50余项,截至目前, 已获授权专利达到30余项,10项发明专利, 属行业内创新龙头企业, 2016年被评为"国家高新技术企业"。

• • •

Zhejiang Huafu Medical Equipment Co., Ltd. was founded in 1983, Committed to the research and development, production and sales of medical devices at home and abroad. The company passed ISO9001 and ISO13485 in 2003 Quality management system certification, currently with TUV (South Germany) ISO13485 quality management system certification and a series of CE products Certification, products sold to more than 30 countries and regions around the world. HUAFU produces a wide range of PPE products and single use medical consumables, the main products include: medical protective clothing, isloation gown, PPE coverall, surgical gown and masks, medical masks, KN95 masks, infusion and transfusion sets, syringes, medical needles, I.V. catheters, medical cannulas, blood sampling products, urine bags, tongue depressors, vaginal speculums, etc.

## FACTORY OVERVIEW 工厂概况

浙江华福位于浙江省嘉兴平湖市国家级经济开发区, 环境清幽、交通便捷(高铁至上海虹桥仅需20分钟)。 公司厂区占地面积4万平方米,总建筑面积3.5万平 方米,拥有符合GMP标准的十万级净化车间面积 14000平方米,拥有员工600余名。

• • •

Zhejiang Huafu is located in Pinghu National Economic Development Zone, Jiaxing City, Zhejiang Province,

The transportation is convenient (it only takes 20 minutes for the high-speed railway to Shanghai Hongqiao).

The company has an area of 40000 square meters, with a construction area of 35000 square meters, it has a GMP standard of 100000 grade purified workshop covering an area of 14000 square meters and has more than 600 employees.





02 针缝粘合工序 Sewing workshop











In order to ensure that there are enough quality inspectors, the company has transferred nearly 50 people to be specialized in quality inspection, and the number of quality inspectors in each workshop is nearly 10.



物

环氧乙烷灭菌器

进料门



## 所有产品均经过仪器严格检测

环氧乙烷灭菌器

THYLENE OXIDE STERILIZER

进料门

杭州申生消毒设备有限公司

All products are strictly tested by instruments



## **PRODUCTION QUALIFICATION AND TECHNICAL CERTIFICATE** 生产资质及技术证明

#### 华福拥有合法的营业执照及医疗器械生产许可证,其生产的医用器 材均获得美国食品和药物管理局认证和德国质量安全认证。

Huafu has legal business license and medical device production license, and its medical devices have obtained FDA certification and TUV safety certification.

Manufac	turer:								SCIDGL	
Address: 083	XINOSING 1ST				ROVINCE, PEOPLE'S RE	UBLIC OF CHINA				11121 112.1121 ***
Europes	in Repres	sentative								
Ti Product Name	ringin Julianip e Hagus, Neth r: Covinal				Tal: +31645171879 E-mail: poter@obsert.o				医疗 ***** =====	器械生产许可
Model: 150cr	1081 180m(5	(i. 170cm)MJ, 11	150m/L), 1800m	PELL Sister P	21.)					100 ALA 80
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		Icol institutions w	warring to prevent	the transmissi	on of the virus from the patien	the medical staff with a	er or liquid.			N
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Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质:无纺布+聚乙烯/TPU膜

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。适用于ICU、重症监护室、医疗机构红区使用。

Material: non-woven fabric + PE / TPU membrane

Coverall Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose.

The structure of the products should be reasonable and convenient, and the combination area be tight. It is suitable for use in ICU, ICU and red area of medical institutions.

Jumpsuit Sp	Jumpsuit Specification Unit: cr								
SIZE	Length	Width	Belts	Sleeve	Tolerance				
160cm	168.5	135	85	26	±2				
165cm	173	140	88	26	±2				
170cm	177.5	145	91	26	±2				
175cm	182	150	94	26	±2				
180cm	186.5	155	97	26	±2				
185cm	191	160	100	26	±2				



TTS

#### 天纺标检测认证股份有阻公司

检验报告



MA

200215340010

天纺标检测认证股份有阻公司

检验报告



C K T C - W T 2 0 0 3 1 0 2 4



							第1页 共4
	委托单位/地址	浙江华福医用器	异材有限公司		送样丿	٨	
	910-PE/ 2020	浙江省嘉兴市平	Z湖市经济开发区新兴	《一路688号	电话:		
	生产单位/地址	浙江华福医用器					
府		浙江省嘉兴市平	学湖市经济开发区新兴	《一路688号			
客		样品名称:	医用隔离服		商标:	华福	
是共言		样品总数:	10件				
息	样品信息	号型规格:	A型连身式(有压胶	)	颜色:		
		质量等级:			安全类别:		
		产品款号或货号:					
	样品描述	1# 白色压浅蓝条					
	检验性质	委托检验	样品受理日期	2020-05-22	报告签	56日期	2020-06-0
	执行标准	GB 19082-2009 GB/T 12704-1991 GB/T 3923. 1-199 GB/T 4744-1997 GB/T 4745-1997					
	检验结论	检验结果及符合	性见附页。				
-11-+	示准检验方法说明			检验单位盖章		认证册	
中枢	小在位短方法说明				-	A work	and the
检验	金结果的不确定度				派	_	展 样
	备注	客户要求所检项目 医用隔离衣标准判	按医疗器械产品技术	要求编号:浙嘉楝	发备20210052	<del>5</del>	No.

CKTC-WT2003102	4					第2页 共4页
检测项目	项目描述	单位	标准值	实测值	评价	方法标准/备注
1# 白色压浅蓝	条					·
规格尺寸*			按标准要求	+	符合	医疗器械产品技术要 求编号:浙嘉械备 20200053号
过滤效率*	非油性颗粒过滤效率	%	≥70	样品1:关键部位材料左前襟, 99, 802右前襟, 99, 805左臂, 99, 807方箭梁, 99, 901右箭梁, 99, 837青部, 99, 845接缝处后颈, 99, 956左腋下: 99, 958下裆, 99, 923青部, 99, 960右腋下: 99, 885样品2:关键部位材料左前襟, 99, 931青部, 99, 960右膝下: 99, 833右前襟, 99, 931方部: 99, 931青部: 99, 931青部: 99, 931青部: 99, 931青部: 99, 845左腋下: 99, 743下裆: 99, 846青腋下: 99, 873样品3:关键鉛位材料左前襟: 99, 955右前襟: 99, 937右臂: 99, 9391右腋下: 99, 991右腋下: 99, 991右腋下: 99, 995	符合	医疗器械产品技术要 求编号:浙嘉械备 20200053号 医疗器械产品技术要
外观*			按标准要求	+	符合	送灯 舔椒厂 面投不安 求编号:浙嘉械备 20200053号
断裂强力		Ν	≥45	纵向: 154 横向: 172	符合	GB/T 3923.1-1997
表面抗湿性		级	$\geq 3$	4	符合	GB/T 4745-1997
抗渗水性		kPa	≥1.67	24.66	符合	GB/T 4744-1997 水压上升速率: 60cmH₂O/min ±3cmH₂O/min
透湿量		g/ (m²•d)	≥2500	3990	符合	GB/T 12704-1991



### 天纺标检测认证股份有阻公司







天纺标检测认证股份有阻公司

检验报告



#### CKTC-WT20031024

_CKTC-WT20031024 第3页 共								
检测项目	项目描述	单位	标准值	实测值	评价	方法标准/备注		
抗合成血液穿透性		级	≥2	6	符合	GB 19082-2009		

表中 "+" 为符合标准要求, "×"表示不符合标准要求, "\*"表示该项目不在CMA授权范围内。

以下空白



MEDICAL COVERALL SUIT MODEL A STYLE 2 医用隔离衣A型 (款式二)



Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质: 聚丙烯+聚乙烯/TPU膜

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。适用于ICU、重症监护室、医疗机构红区使用。

#### Material: PP+PE / TPU membrane

Coverall Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose.

The structure of the products should be reasonable and convenient, and the combination area be tight. It is suitable for use in ICU, ICU and red area of medical institutions.

Jumpsuit Sp	ecification				Unit: cm
SIZE	Length	Width	Belts	Sleeve	Tolerance
160cm	168.5	135	85	26	±2
165cm	173	140	88	26	±2
170cm	177.5	145	91	26	±2
175cm	182	150	94	26	±2
180cm	186.5	155	97	26	±2
185cm	191	160	100	26	±2
190cm	195.5	165	103	26	±2

SGS	OCAL IT BESCUL EXH EXH CALL LOSS	SGS	81,52025257			NAS	PIBLIE MBG2U, 558 TESTING CNAS L0000 Page 3 of 4	
	L52025257886401TE Date May 20,2020 Page 1 of 4 L DOLIPMENT COLTD TRUMUL 2014/00012 PECMINES 215000 CHINA	Barrier performance of						Test Report SL52025257895401TX Date:May 20,2020 Page 4 c
	were submitted and identified on behalf of the client as: (A)Coverall(isolation gown)		Impact Penetration Test AXTCC 42(s)	Hydrostatic Pressare Test A&TDD 1220/mH208	Pesistance to Bacteriophage Phi-X174 ASTM F 16T1	Level	Final classification	Service Proto
	XL (Appiyester + PE	Area A (Critical zone- tront)	0.0	7.85	/	Level 1		
Sample Color :	(A)white	Area B (Critical zono-	0.0	>50.0	1	Level 3		
Manufacturer : Suppler :	2HEJANG HUAFU MEDICAL EQUIPMENT COLLTD 2HEJANG HUAFU MEDICAL EQUIPMENT COLLTD	Area C (Critical zone-	0.0	>50.0	7	Level 2		SHE SHE
		Back) Seam between areas	0.0	>50.0		Level 3	Level 1	
ample Receiving Date : esting Period :	May 18, 2020 May 18, 2020 - May 20, 2020	A68 Seam between areas	0.0	-50.0		Level 3		
		A&C Seam between areas	0.0	>50.0		Level 3		
est Parsuit(s)	Unless otherwise stated the results shown in this test report refer only to the sample(s) leated, for further details, please refer to the following page(s).	BSC Barnadi	0.0	>0.0<	1	Level 3		Face Back
		PB70-2012 is not eth	icked.					
Signed for and on behalf of SGS-CSTC Standards Techn	ical Services (Stranghai) Co., Ltd Testing Detter							
Sara Gan								
Sara Guo (Account Executive	4							
		alla						

## MEDICAL COVERALL SUIT MODEL B 医用隔离衣 B型



Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质:无纺布+聚丙烯/TPU膜

隔离衣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。产品结构应合理,穿脱方便,结合部位严密;关键部位材料的断裂强力应不小于45N。 不适用于ICU、重症监护室、医疗机构红区使用。

Material: non-woven fabric + PE / TPU membrane

Coverall Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination

area be tight; the fracture strength of the material in the key area should not be less than 45N.

It is not suitable for use in ICU, ICU and red area of medical institutions.

• Jumpsuit Sp	Jumpsuit Specification Unit: cn								
SIZE	Length	Width	Belts	Sleeve	Tolerance				
160cm	168.5	135	85	26	±2				
165cm	173	140	88	26	±2				
170cm	177.5	145	91	26	±2				
175cm	182	150	94	26	±2				
180cm	186.5	155	97	26	±2				
185cm	191	160	100	26	±2				
190cm	195.5	165	103	26	±2				





Test Report	SL52025258573401TX	Date:May 28,2020	Page 1 of 4					
	ICAL EQUIPMENT CO., LTD. D, PINGHU, JIAXING, ZHEJIA	NG PROVINCE, 314200 CHINA						
The following sample(s) was/were submitted and identified on behalf of the client as:								
Sample Description	: (A)Coverall(isolation gov	vn)						
Style No. Composition Sample Color Manufacturer Supplier		DICAL EQUIPMENT CO., LTD. DICAL EQUIPMENT CO., LTD.						
Sample Receiving Date Testing Period	: May 26, 2020 : May 26, 2020 - May 28,	2020						
Test Result(s)		the results shown in this test report re her details, please refer to the followin						
Test Performed	: Selected test(s) as reque	ested by applicant						

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

Sara Guo (Account Executive)





**Test Report** SL52025258573401TX Date:May 28,2020 Page 2 of 4

Test Result

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)	0.4	0.2	0.2	0.2	0.3
Area B (Critical zone-sleeve)	0.3	0.2	0.3	0.4	0.2
Area C (Critical zone-Back)	3.0	0.7	0.2	0.2	4.2
Seam between areas A&B	2.6	3.7	3.4	3.2	3.1
Seam between areas A&C	3.2	3.7	0.2	0.2	0.4
Seam between areas B&C	3.7	2.4	3.3	2.2	3.1
Remark:					

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

٠ 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) .



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中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

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3<sup>rd</sup>Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn 中国・上海・徐汇区宜山路889号3号楼 邮编: 200233 e sas.china@sas.com t (86-21) 61402666 f (86-21) 64958763







中国认可 国际互认 检测 TESTING CNAS L0599

Test Report

SL52025258573401TX

Date:May 28,2020

Page 4 of 4

#### Barrier performance of each component and final classification commended.

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH <sub>2</sub> O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone- front)	0.4	/	/	Level 1	
Area B (Critical zone- sleeve)	0.4	/	/	Level 1	
Area C (Critical zone- Back)	4.2	/	/	Level 1	Level 1
Seam between areas A&B	3.7	/	/	Level 1	Lever
Seam between areas A&C	3.7	/	/	Level 1	
Seam between areas B&C	3.7	/	/	Level 1	

#### 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 1: Impact Penetration Test-AATCC 42: ≤4.5g;
- Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH<sub>2</sub>O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH<sub>2</sub>O;
- Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.
- Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.



\*\*\*End of Report\*\*\*



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## MEDICAL USE ISOLATION GOWN MODEL C STYLE 1 医用隔离衣 C型 (款式一)



Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质: SMS/聚丙烯+聚乙烯

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。

#### Material: SMS/PP+PE

Isolation gown Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination area be tight.

#### 其他:可定制尺寸、克重 Other: Customizeed size&weight.

• Jumpsuit Sp	Jumpsuit Specification Unit: c								
SIZE	Length	Width	Belts	Sleeve	Tolerance				
S	107	63	61	61	±2				
М	107	68	61	62	±2				
L	117	68	61	63	±2				
XL	127	73	61	64	±2				
XXL	137	78	61	64	±2				





Test Report



Date:June 01,2020



Page 1 of 4

ZHEJIANG HUAFU MEDICAL EQUIPMENT CO.LTD NO.688 XINXING 1ST RD. PINGHU, JIAXING, ZHEJIANG PROVINCE, 314200 CHINA

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

SL52025258954601TX

Sample Description	:	(A)Isolation gown
Composition	:	(A)SMS
Sample Color	:	(A)blue
Manufacturer	:	ZHEJIANG HUAFU MEDICAL EQUIPMENT CO.LTD
Supplier	:	ZHEJIANG HUAFU MEDICAL EQUIPMENT CO.LTD
Sample Receiving Date Testing Period	:	May 28, 2020 May 28, 2020 - Jun 01, 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)



**Test Report** SL52025258954601TX Date:June 01,2020 Page 2 of 4

Test Result

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

71010001100					
Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	0.0	0.0	0.0	0.0	0.0
Area B (Critical zone-sleeve)	0.0	0.0	0.0	0.0	0.0
Area C (Critical zone-Back)	0.0	0.0	0.0	0.0	0.0
Seam between areas A&B	0.0	0.0	0.0	0.0	0.0
Seam between areas A&C	0.0	0.0	0.0	0.0	0.0
Seam between areas B&C	0.0	0.0	0.0	0.0	0.0
Remark:					

Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5grams(g) ٠

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 <sub>2</sub> O)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	>50.0	>50.0	>50.0	30.2	38.9
Area B (Critical zone-sleeve)	>50.0	>50.0	>50.0	>50.0	>50.0
Area C (Critical zone-Back)	>50.0	>50.0	>50.0	>50.0	31.1
Seam between areas A&B	>50.0	>50.0	>50.0	29.0	>50.0
Seam between areas A&C	>50.0	>50.0	>50.0	>50.0	20.8
Seam between areas B&C	>50.0	>50.0	>50.0	44.6	41.1
Remark:					

 Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH<sub>2</sub>O •

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



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**Test Report** 

Date:June 01,2020

Page 4 of 4

Barrier performance of each component and final classification commended

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH2O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone- front)	0.0	30.2	1	Level 2	
Area B (Critical zone- sleeve)	0.0	>50.0	1	Level 3	
Area C (Critical zone- Back)	0.0	31.1	1	Level 2	Level 2
Seam between areas A&B	0.0	29.0	/	Level 2	Level 2
Seam between areas A&C	0.0	20.8	1	Level 2	
Seam between areas B&C	0.0	41.1	1	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 1: Impact Penetration Test-AATCC 42: ≤4.5g; •
- Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH<sub>2</sub>O; ٠
- Level 3: Impact Penetration Test-AATCC 42: <1.0g; Hydrostatic Pressure Test-AATCC 127: >50cmH<sub>2</sub>O; ٠
- Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass. ٠
- Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI ٠ PB70-2012 is not checked.



Sample Photo

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#### MEDICAL USE ISOLATION GOWN MODEL C STYLE 2





Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质: SMS/聚丙烯+聚乙烯

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。

#### Material: SMS/PP+PE

Isolation gown Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination area be tight.

#### **其他:**可定制尺寸、克重 **Other:** Customizeed size&weight.

• Jumpsuit Sp	ecification				Unit: cm
SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
М	107	68	61	62	±2
L	117	68	61	63	±2
XL	127	73	61	64	±2
XXL	137	78	61	64	±2



## MEDICAL USE ISOLATION GOWN MODEL C STYLE 2 医用隔离衣 C型 (款式三)

#### Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质:针织布+TPU膜/PP+PE

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。

#### Material: woven fabric+TPU membrane/PP+PE

Isolation gown Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination area be tight.

#### **其他:**可定制尺寸、克重 **Other:** Customizeed size&weight.

• Jumpsuit Sp	ecification				Unit: cm
SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
М	107	68	61	62	±2
L	117	68	61	63	±2
XL	127	73	61	64	±2
XXL	137	78	61	64	±2



## MEDICAL USE ISOLATION GOWN MODEL D (STYLE 1) 医用隔离衣 D型 (款式一)



Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质: 聚丙烯+聚乙烯/无纺布

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。

#### Material: PP+PE/SS

Isolation gown Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination area be tight.

#### **其他:**可定制尺寸、克重 **Other:** Customizeed size&weight.

• Jumpsuit Sp	ecification				Unit: cm
SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
М	107	68	61	62	±2
L	117	68	61	63	±2
XL	127	73	61	64	±2
XXL	137	78	61	64	±2

#### Test Report / 检测报告







PAGE 19/20 I 产品展示

### MEDICAL USE ISOLATION GOWN MODEL D () 医用隔离衣 D型 ()





Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### 材质: 聚丙烯+聚乙烯/无纺布

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。

#### Material: PP+PE/SS

Isolation gown Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination area be tight.

#### **其他:**可定制尺寸、克重

**Other:** Customizeed size&weight.

• Jumpsuit Sp	ecification				Unit: cm
SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
М	107	68	61	62	±2
L	117	68	61	63	±2
XL	127	73	61	64	±2
XXL	137	78	61	64	±2







## MEDICAL USE ISOLATION GOWN MODEL D 医用隔离衣 D型





Detail Show / 产品细节展示



#### Main Parameters / 主要参数

#### **材 质:** 100% 氯化聚乙烯

隔离衣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。产品结构应合理,穿脱方便,结合部位严密。

#### Material: 100% CPE

Isolation gown Products are usually made by cutting and sewing using non-woven fabric as the main raw material. The product is for non-sterile and single-use purpose. The structure of the products should be reasonable and convenient, and the combination area be tight.

#### **其他:**可定制尺寸、克重

Other: Customizeed size&weight.

• Jumpsuit Sp	ecification				Unit: cm
SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
М	107	68	61	62	±2
L	117	68	61	63	±2
XL	127	73	61	64	±2
XXL	137	78	61	64	±2



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住所: 平湖经济开发区新兴一路 688 号	发证部门:浙江省药品、管理》语
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Listing No.	Premarket Submission Number/Type	Product Code(s)	Device Name	Activities
D346787	K003854	FPA	Set, administration, intravascular	Manufacturer
D374391	Exempt	OEA	Non-surgical isolation gown	Manufacturer
D331226	Exempt	КҮХ	DISPENSER, LIQUID MEDICATION	Manufacturer
D352530	Exempt	FMA	DEPRESSOR, TONGUE, NON-SURGICAL	Manufacturer
D376645	Exempt	КНА	MASK, SCAVENGING	Manufacturer

Page Last Updated: 03/30/2020



# 根据不同规格型号,有四种合格证类型

According to different specifications and models, there are four quality certificate.

## Size:90X120cm





## Size:90X120cm

合格证 QUALITY CERTIFICATE 产品名称: 医用隔离衣 Fundam: GAIME A Medical Use Isolation Gown 規格型号Specification: D型 Type D 检验工号Checker No: 08 生产批号LOT No: 200520 生产日期MFG DATE: 2020-05-20 生产日期MFG DATE: 2020-05-20 有效期EXP DATE:三年/3years 执行标准 Standard: 医用隔离衣技术要求浙嘉械备20200053号 Medical isolation gown technical requirements from No: 20200053 Records 产品成分Materials: 55%聚丙烯、45%聚乙烯 55%Polypropylene、45%Polyethylene [注意事项] 本品限一次性使用,非无菌提供; 内包装破损、过期产品禁止使用; 使用后废弃物,按照《医疗废物管理条例》等规定处理,防止误用或者混用。 Precautions: This product is single use and non-sterile; damaged and expired products are prohibited to use. After use, the waste shall be disposed of in accordance with the Medical Waste Management Ordinance and other provisions to prevent misuse or mixed use accordance with the Medical Waste Management Ordinance and other provisions to prevent misuse or mixed use. 包装规格 Packing specification: 1件/包 1 Piece/Bag 医疗器械备案证号: 浙嘉械备20200053号 生产备案凭证编号: 浙嘉械备20200053号 产品技术要求编号: 浙嘉械备20200053号 浙江华福医用器材有限公司 ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., NTD 住所: 浙江省平湖市经济开发区新兴 路68号 Address: NO.688, XINXING IST RD., PINGTU, JIAXING, ZHEJIANG PROVINC 314200 CHINA 生产地址: 浙江省平湖市经济开发区新兴 PKC00 号人 生产地址:浙江省平湖市经济开发区新兴一路688号公AITELANG Production address: NO.688, XINXING IST RD, INGHUMAXING, THE JANG PROVINCE, 314200 CHINA 电话PHONE: +86 573-85963333 MADE IN CHINA







1件/包 1PIECE/BAG 40件/箱 40PCS/CTN 毛重: 10.94 Kgs GW:10.94 kgs 净重: 9.4 kgs NW:9.4 kgs



## Carton size:60X40X40cm

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