

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

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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

BRIEF INTRODUCTION

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, isolation 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.

质量重于生命，企业在于创新

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

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.



01

原材料生产

Raw material production

02

针缝粘合工序

Sewing workshop



03

热合密封加工

Heat sealing processing





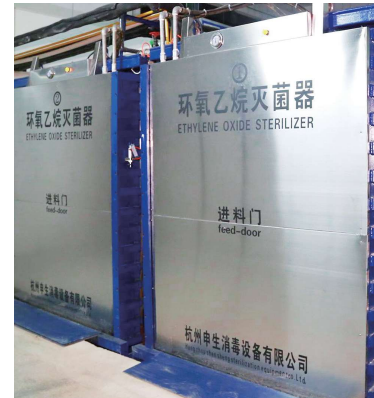
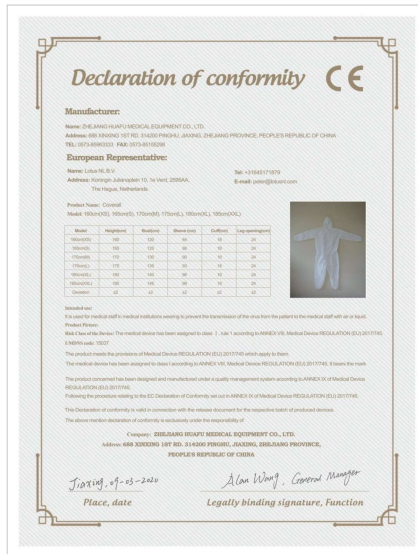
GB 19082-2009
Medical Coverall Suit

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.

所有产品均经过仪器严格检测
All products are strictly tested by instruments



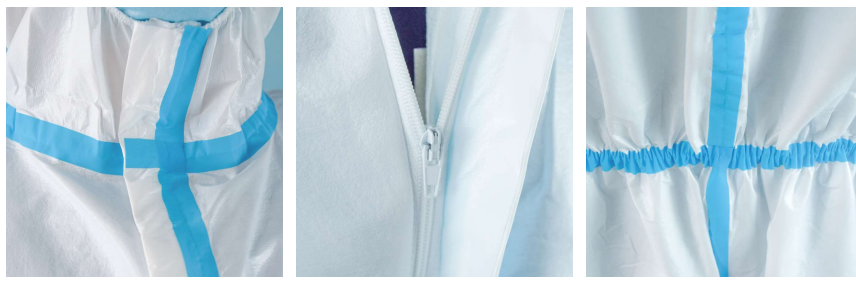
为了保证有足够的质检人员，公司抽调了近50人专门从事质检，每个车间的质检人员数量近10人。

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.

MEDICAL COVERALL SUIT MODEL A STYLE 1
医用隔离衣 A型 (款式一)



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 Specification**

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

Test Report / 检测报告



检验报告



200215340010



CKTC-WT20031024

第1页 共4页

客户 提供 信息	委托单位/地址	浙江华福医用器材有限公司 浙江省嘉兴市平湖市经济开发区新兴一路688号			送样人: --- 电话: ---
	生产单位/地址	浙江华福医用器材有限公司 浙江省嘉兴市平湖市经济开发区新兴一路688号			
	样品信息	样品名称:	医用隔离服	商标:	华福
		样品总数:	10件	号型规格:	A型连身式(有压胶)
	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	报告签发日期	2020-06-01
执行标准	GB 19082-2009 GB/T 12704-1991 GB/T 3923.1-1997 GB/T 4744-1997 GB/T 4745-1997				
检验结论	检验结果及符合性见附页。 检验单位盖章				
非标准检验方法说明	-----				
检验结果的不确定度	-----				
备注	客户要求所检项目按医疗器械产品技术要求编号:浙嘉械备2020053号 医用隔离衣标准判定。				

批准:

单学菁

审核:

何新

编制:

检测师印章



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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: 99.895 左臂: 99.901 右臂: 99.837 背部: 99.845 接缝处 后颈: 99.956 左腋下: 99.958 下档: 99.923 背部: 99.960 右腋下: 99.885 样品2: 关键部位材料 左前襟: 99.933 右前襟: 99.921 左臂: 99.930 右臂: 99.931 背部: 99.927 接缝处 后颈: 99.903 左腋下: 99.743 下档: 99.816 背部: 99.894 右腋下: 99.873 样品3: 关键部位材料 左前襟: 99.955 右前襟: 99.885 左臂: 99.937 右臂: 99.981 背部: 99.901 接缝处 后颈: 99.977 左腋下: 99.905 下档: 99.892 背部: 99.991 右腋下: 99.965	符合	医疗器械产品技术要求编号:浙嘉械备20200053号
外观*	---	---	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
断裂强力	---	N	≥45	纵向: 154 横向: 172	符合	GB/T 3923.1-1997
表面抗湿性	---	级	≥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: 60cmH ₂ O/min ±3cmH ₂ O/min
透湿量	---	g/(m ² ·d)	≥2500	3990	符合	GB/T 12704-1991



检验报告



200215340010

CKTC-WT20031024

第3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
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。

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检验报告



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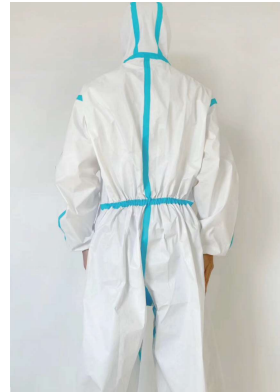
第4页 共4页

样 品



MEDICAL COVERALL SUIT MODEL A 医用隔离衣 A型

STYLE 2 (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.

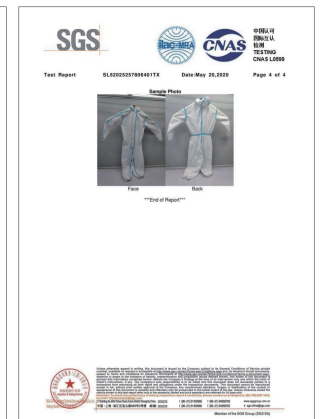
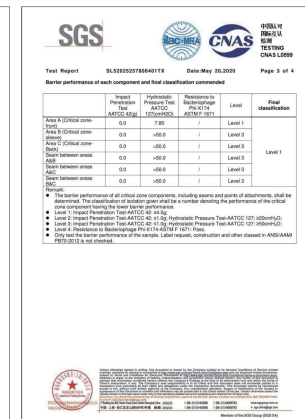
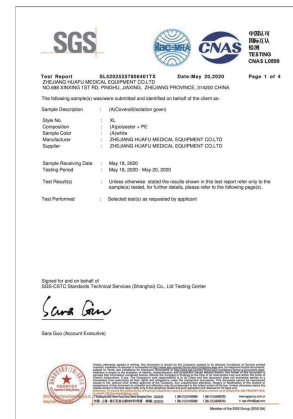
The structure of the products should be reasonable and convenient, and the combination area be tight. It is suitable for use in ICU, ICU and red area of medical institutions.

● Jumpsuit Specification

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

Test Report / 检测报告



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.

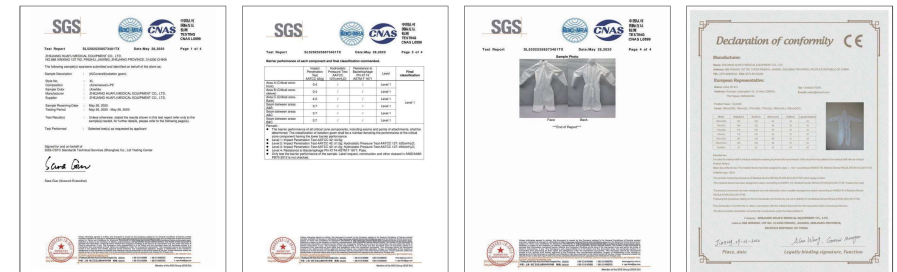
It is not suitable for use in ICU, ICU and red area of medical institutions.

Jumpsuit Specification

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

Test Report / 检测报告





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CNAS L0599

Test Report SL52025258573401TX Date: May 28, 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:

Sample Description : (A)Coverall(isolation gown)
Style No. : XL
Composition : (A)nonwoven+PE
Sample Color : (A)white
Manufacturer : ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
Supplier : ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
Sample Receiving Date : May 26, 2020
Testing Period : May 26, 2020 - May 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 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:
- 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)



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CNAS L0599

Test Report SL52025258573401TX Date: May 28, 2020 Page 3 of 4

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)	0.4	/	/	Level 1	Level 1
Area B (Critical zone-sleeve)	0.4	/	/	Level 1	
Area C (Critical zone-Back)	4.2	/	/	Level 1	
Seam between areas A&B	3.7	/	/	Level 1	
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: ≥20cmH₂O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH₂O;
- 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.



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

Sample Photo



Face

Back

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.

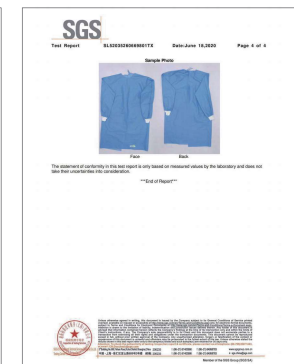
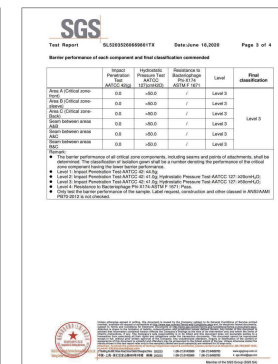
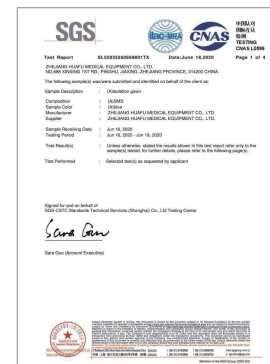
其他: 可定制尺寸、克重 **Other:** Customized size&weight.

Jumpsuit Specification

Unit: cm

SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
M	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





中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report SL52025258954601TX **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:

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 : May 28, 2020
Testing Period : 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)



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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

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)
- 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)	>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 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(cmH2O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone-front)	0.0	30.2	/	Level 2	Level 2
Area B (Critical zone-sleeve)	0.0	>50.0	/	Level 3	
Area C (Critical zone-Back)	0.0	31.1	/	Level 2	
Seam between areas A&B	0.0	29.0	/	Level 2	
Seam between areas A&C	0.0	20.8	/	Level 2	
Seam between areas B&C	0.0	41.1	/	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: ≥20cmH₂O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH₂O;
- 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.

Sample Photo



Face Back

End of Report

MEDICAL USE ISOLATION GOWN MODEL C

STYLE 2

医用隔离衣 C型 (款式二)



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

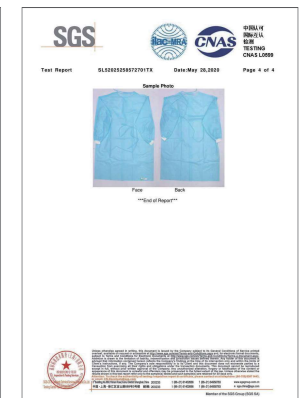
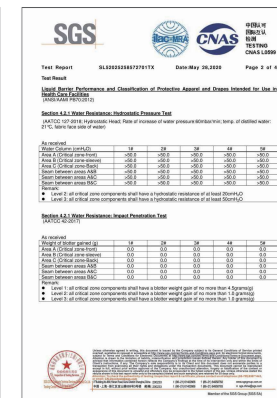
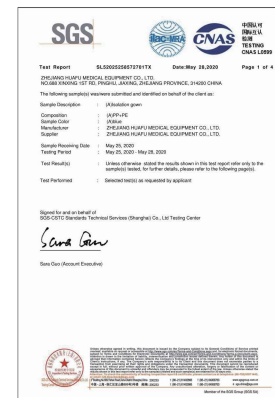
Other: Customized size&weight.

● Jumpsuit Specification

Unit: cm

SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
M	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



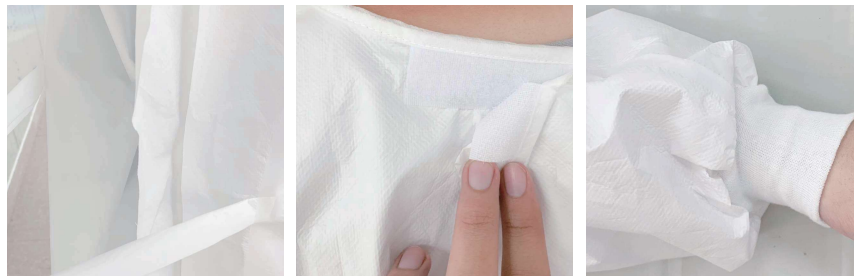
MEDICAL USE ISOLATION GOWN MODEL C

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

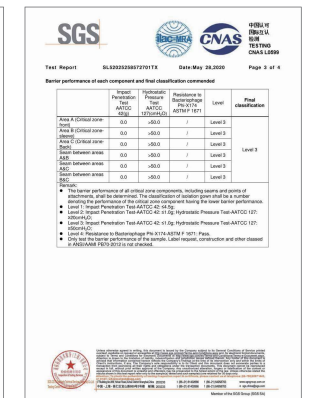
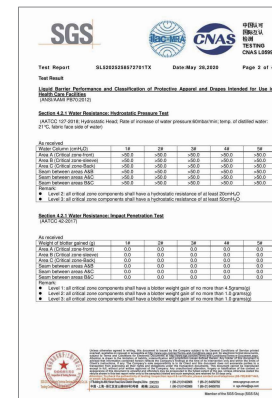
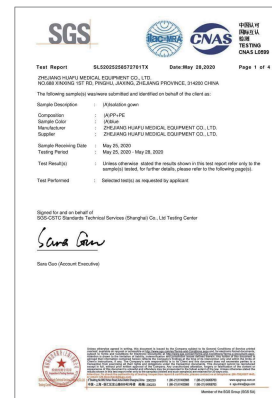
Other: Customized size&weight.

Jumpsuit Specification

Unit: cm

SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
M	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



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:** Customized size&weight.

• **Jumpsuit Specification**

Unit: cm

SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
M	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



MEDICAL USE ISOLATION GOWN MODEL D

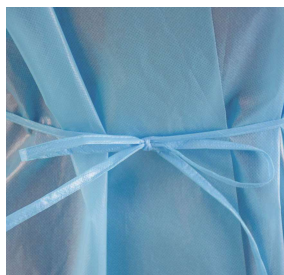
医用隔离衣 D型

(STYLE 2)

(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/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: Customized size&weight.

Jumpsuit Specification

Unit: cm

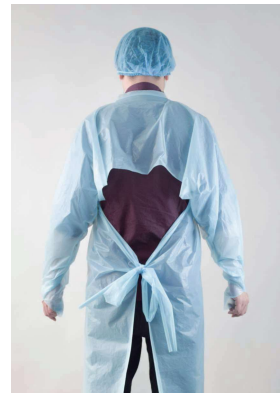
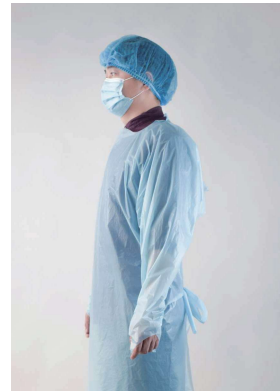
SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
M	107	68	61	62	±2
L	117	68	61	63	±2
XL	127	73	61	64	±2
XXL	137	78	61	64	±2

Test Report / 检测报告

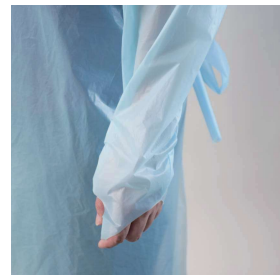
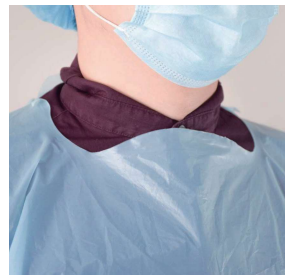


MEDICAL USE ISOLATION GOWN MODEL D
医用隔离衣 D型

(STYLE 3)
(款式三)



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.

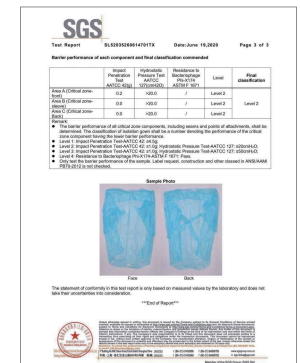
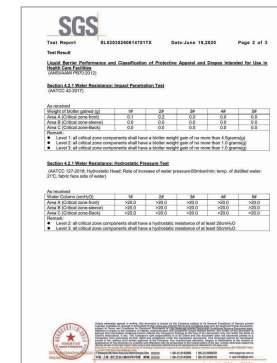
其他: 可定制尺寸、克重 Other: Customized size&weight.

• Jumpsuit Specification

Unit: cm

SIZE	Length	Width	Belts	Sleeve	Tolerance
S	107	63	61	61	±2
M	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



医疗器械生产许可证

许可证编号：浙食药监械生产许20100231号

企业名称：浙江华福医用器材有限公司
生产地址：浙江省平湖市经济开发区新兴一路688号

法定代表人：王维文
生产范围：第三、二类14-02血管内输液器械；第二类14-14医护人员防护用品***

企业负责人：王维文

住所：平湖经济开发区新兴一路688号
发证部门：浙江省药品监督管理局

有效期限：至2025年3月29日
发证日期：2020年3月30日

国家食品药品监督管理总局制

第一类医疗器械备案凭证

浙江华福医用器材有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用隔离衣予以备案，备案号：浙嘉械备20200053号。

嘉兴市市场监督管理局

(盖章)

日期：2020年04月29日

统一社会信用代码
91330482148405063L (1/1)

营业执照



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名称 浙江华福医用器材有限公司
类型 有限责任公司(自然人投资或控股)
法定代表人 王维文
经营范围 生产：6681-1第三类输液、输血器具及管路；6815第三类注射穿刺器械；6815第二类注射穿刺器械(《医疗器械生产许可证》有效期至2020年4月12日)；塑料加工专用设备、塑料模具加工制造。 批发、零售：化工辅料(不含危险化学品及易制毒品)；货物进出口、技术进出口(国家法律禁止、限制的项目除外)。(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 壹仟万元整
成立日期 1994年08月24日
营业期限 1994年08月24日至2024年08月23日
住所 浙江省平湖市经济开发区新兴一路688号

登记机关



2019年05月21日

国家企业信用信息公示系统网址：<http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过国家信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制



Fiscal Year 2020
CERTIFICATE OF FDA REGISTRATION

This certifies that
ZHEJIANG HUAFU MEDICAL EQUIPMENT CO.,LTD
NO.688 Xinxing 1st Rd., Pinghu, Jiaxing, Zhejiang Province, China

Has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration,
 through MEDISCA Inc
 Owner/Operator Number:3014720527

UNITED STATES AGENT
Contact Name: Ben Arts
Contact Title: Mr
Business Name: MEDISCA Inc

Address: 661 Route 3 Unit C
 Plattsburgh, New York, UNITED STATES
Phone: 518-5634636
E-mail: Barts@medisca.com

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	KYX	DISPENSER, LIQUID MEDICATION	Manufacturer
D352530	Exempt	FMA	DEPRESSOR,TONGUE, NON-SURGICAL	Manufacturer
D376645	Exempt	KHA	MASK, SCAVENGING	Manufacturer

Please careful protect your Listing Number.

Medisca Inc
 661 Route 3 Unit C
 Plattsburgh, New York, UNITED STATES

Cert. No.: M20323
Issued Date: 23 March 2020
Expiration Date: 31 December 2020

US FDA Listed No.: D374391

U.S. Department of Health & Human Services
 U.S. FOOD & DRUG ADMINISTRATION

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

Establishment Registration & Device Listing

1 result found for **Owner Operator Number :** 10058618

Establishment Name	Registration Number	Current Registration Yr
ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD. CHINA	3014720527	2020
<ul style="list-style-type: none"> Depressor, Tongue, Non-Surgical - Tongue Depressor Non-Surgical Isolation Gown - Coverall Set, Administration, Intravascular - Infusion Set Dispenser, Liquid Medication - Oral Syringe Mask, Scavenging - Medical Mask 		Manufacturer

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U.S. Food and Drug Administration
 10903 New Hampshire Avenue

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	KYX	DISPENSER, LIQUID MEDICATION	Manufacturer
D352530	Exempt	FMA	DEPRESSOR,TONGUE, NON-SURGICAL	Manufacturer
D376645	Exempt	KHA	MASK, SCAVENGING	Manufacturer

Label in the box 盒内标签

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

合格证 QUALITY CERTIFICATE

产品名称: 医用隔离衣
PRODUCT NAME: Medical Coverall Suit
规格型号 Specification: A型 Type A
检验工号 Checker No: 08
生产批号 LOT No: 200520
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 Coverall Suit technical requirements from No: 20200053 Records
产品成分 Materials: 65%聚酯纤维、35%透气膜
65% Polyester+35% Breathable Film
【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.
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: 浙嘉食药监械生产备20170011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.,LTD
住所: 浙江省平湖市经济开发区新兴一路688号
Address: NO.688, XINXING 1ST RD., PINGHU, JIAXING, ZHEJIANG PROVINCE, 314200 CHINA
生产地址: 浙江省平湖市经济开发区新兴一路688号
Production address: NO.688, XINXING 1ST RD., PINGHU, JIAXING, ZHEJIANG PROVINCE, 314200 CHINA
电话PHONE: +86 573-85963333
MADE IN CHINA

合格证 QUALITY CERTIFICATE

产品名称: 医用隔离衣
PRODUCT NAME: Medical Coverall Suit
规格型号 Specification: B型 Type B
检验工号 Checker No: 08
生产批号 LOT No: 200520
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 Coverall Suit technical requirements from No: 20200053 Records
产品成分 Materials: 65%聚酯纤维、35%透气膜
65% Polyester+35% Breathable Film
【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.
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: 浙嘉食药监械生产备20170011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
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Production address: NO.688, XINXING 1ST RD., PINGHU, JIAXING, ZHEJIANG PROVINCE, 314200 CHINA
电话PHONE: +86 573-85963333
MADE IN CHINA

合格证 QUALITY CERTIFICATE

产品名称: 医用隔离衣
PRODUCT NAME: Medical Use Isolation Gown
规格型号 Specification: C型 Type C
检验工号 Checker No: 08
生产批号 LOT No: 200520
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: 65%聚丙烯、35%聚乙烯
65% Polypropylene, 35% 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.
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: 浙嘉食药监械生产备20170011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.,LTD
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Address: NO.688, XINXING 1ST RD., PINGHU, JIAXING, ZHEJIANG PROVINCE, 314200 CHINA
生产地址: 浙江省平湖市经济开发区新兴一路688号
Production address: NO.688, XINXING 1ST RD., PINGHU, JIAXING, ZHEJIANG PROVINCE, 314200 CHINA
电话PHONE: +86 573-85963333
MADE IN CHINA

Label in the box 盒内标签

Size:90X120cm

合格证

QUALITY CERTIFICATE

产品名称: 医用隔离衣
PRODUCT NAME: Medical Use Isolation Gown
规格型号 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
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.
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: 浙嘉食药监械生产备20170611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., LTD
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PROVINCE, 314200 CHINA
电话 PHONE: +86 573-85963333
MADE IN CHINA



真空塑封包装 1件/包 1Piece/Bag



OUTER PACKING 外箱包装

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

