



DISPOSABLE MEDICAL PROTECTIVE CLOTHING



ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.

Add: No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200 China.

Tel: 0573-85963333 Fax: 0573-85155298

Http://www.huafuzj.com E-mail: sales@huafuzj.com

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

PRODUCT STANDARD GB 19082-2009

医用一次性防护服

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立于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用具，主要产品：医用
防护服、一次性防护服、外科手术隔离衣、
医用口罩、外科医用口罩、Kn95、N95等。



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 mainly produces medical protective
equipment, main products: Medical
Protective clothing, disposable protective
clothing, surgical isolation clothing
Medical masks, surgical masks, kn95, N95, 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

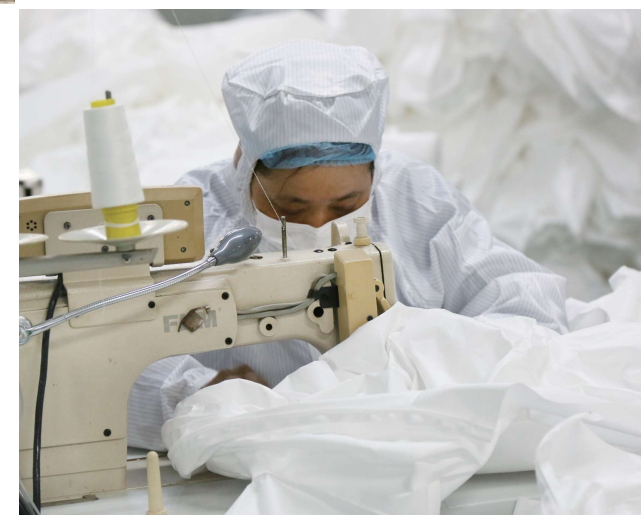
原材料生产

Raw material production

02

针缝粘合工序

Sewing workshop



03

热合密封加工

Heat sealing processing





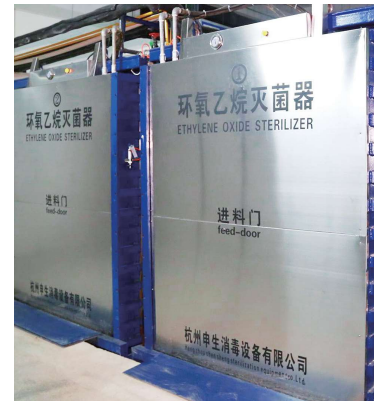
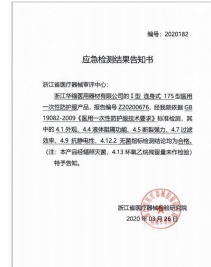
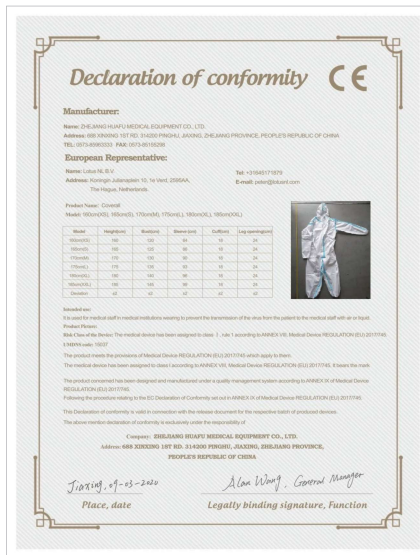
GB 19082-2009
Disposable Medical Protective Clothing

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。

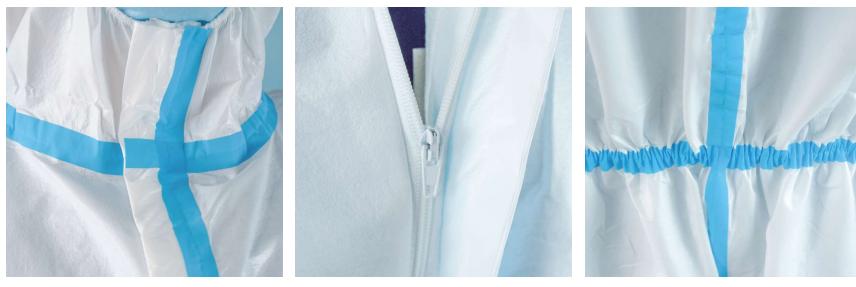
In order to ensure that there are enough quality inspectors, the company has transferred nearly 50 people to be specialized in quality inspection, and the number of quality inspectors in each workshop is nearly 10.

DISPOSABLE MEDICAL PROTECTIVE CLOTHING

医用一次性防护服



Detail Show / 产品细节展示



Main Parameters / 主要参数

医用一次性防护服产品为连身式结构，由连帽上衣、裤子组成。产品执行GB 19082-2009《医用一次性防护服技术要求》（除阻燃性能、抗静电性、静电衰减性能外）。

The Disposable medical protective clothing adopts a jumpsuit structure, which is composed of the hooded top and pants. The product implements the GB 19082-2009 Technical Requirements for Medical Disposable Protective Clothing (except for flame retardant performance, anti-static resistance, static decay performance).

● 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

The image displays several documents related to the product's testing and certification. It includes a main 'TEST REPORT' (检验检测报告) with a table of test results, detailed 'Testing Results' (检测报告) for various parameters, and a 'Declaration of conformity' (CE) certificate. The reports are issued by HANGJIAO TESTING SERVICE CO., LTD. and feature logos for MA, CNAS, and other accreditation bodies.

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

中华人民共和国医疗器械注册证

注册证编号：浙械注准20202141121

注册人名称	浙江华福医用器材有限公司
注册人住所	浙江省平湖市经济开发区新兴一路688号
生产地址	浙江省平湖市经济开发区新兴一路688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	型号：无菌型；规格：160、165、170、175、180、185。
结构及组成	产品为连体式，由连帽上衣、裤子组成。
适用范围	供临床医务人员在工作时接触到的具有潜在感染性的患者血液、体液、分泌物等提供阻隔、防护用。
附件	产品执行GB 19082-2009《医用一次性防护服技术要求》（除4.2结构、4.3号型规格、4.6断裂伸长率、4.8阻燃性能、4.10静电衰减性能、4.11皮肤刺激性、4.12.1微生物指标（不适用）、4.13环氧乙烷残留量（辐照灭菌，不适用）外）。
其他内容	/
备注	本产品为防控新型冠状病毒感染的肺炎疫情应急审批产品，注册证有效期为6个月，产品标签和说明书上应醒目标注“仅供防控疫情应急使用”。

审批部门：浙江省药品监督管理局

批准日期：2020年03月03日
 有效期至：2020年09月03日
 注册证编号：浙械注准20202141121

营业执照

统一社会信用代码
91330482148405063L (1/1)



扫描二维码“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息

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 日通过国家信用公示系统报送公示年度报告。

国家市场监督管理总局监制



检测报告 · 多项检测符合国家标准

编号: 2020182

应急检测结果告知书

浙江省医疗器械审评中心:

浙江华福医用器材有限公司的 I 型 连身式 175 型医用一次性防护服产品, 报告编号 Z20200676, 经我院依据 GB 19082-2009 《医用一次性防护服技术要求》标准检测, 其中的 4.1 外观、4.4 液体阻隔功能、4.5 断裂强力、4.7 过滤效率、4.9 抗静电性、4.12.2 无菌指标检测结论均为合格。

(注: 本产品经辐照灭菌, 4.13 环氧乙烷残留量未作检验) 特予告知。



浙江省医疗器械检验研究院

2020年03月26日


Declaration of conformity CE

Manufacturer:
 Name: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
 Address: 688 XINXING 1ST RD. 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA
 TEL: 0573-85963333 FAX: 0573-85155298

European Representative:
 Name: Lotus NL B.V. Tel: +31645171879
 Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. E-mail: peter@lotusnl.com

Product Name: Protective Clothing
 Specification: 160(S), 165(M), 170(L), 175(XL), 180(XXL), 185(XXXL), 190(XXXXL)

Specification	Height(cm)	Bust(cm)	Sleeve(cm)	Cuff(cm)	Leg opening(cm)
160(S)	168.5	135	85	20	24
165(M)	173	140	88	20	24
170(L)	177.5	145	91	20	24
175(XL)	182	150	94	20	24
180(XXL)	186.5	155	97	20	24
185(XXXL)	191	160	100	20	24
190(XXXXL)	195.5	165	103	20	24
Deviation	±2cm	±2cm	±2cm	±2cm	±2cm



Intended use:
 It is used for medical staff in medical institutions wearing to prevent the transmission of the virus from the patient to the medical staff with air or liquid.

Product Picture:
 Risk Class of the Device: The medical device has been assigned to class I, rule 1 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745.
 UMDNS code: 15037
 The product meets the provisions of Medical Device REGULATION (EU) 2017/745 which apply to them.
 The medical device has been assigned to class I according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745. It bears the mark

The product concerned has been designed and manufactured under a quality management system according to ANNEX IX of Medical Device REGULATION (EU) 2017/745.
 Following the procedure relating to the EC Declaration of Conformity set out in ANNEX IX of Medical Device REGULATION (EU) 2017/745.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
 The above mention declaration of conformity is exclusively under the responsibility of

Company: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
 Address: 688 XINXING 1ST RD. 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE,
 PEOPLE'S REPUBLIC OF CHINA

Jiaxing, 09-03-2020
 Place, date

Alan Wang, General Manager
 Legally binding signature, Function



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 24 april 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Wei,

Graag bevestig ik hierbij de ontvangst op 9 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Zhejiang Huafu Medical Equipment Co.,Ltd met Europees gemachtigde Lotus NL B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

**Medical face mask(non-sterile),Protective clothing(non-sterile)
(geen merknaam) (NL-CA002-2020-50404)**

Toekomstige wijzigingen in bovengenoemde gegevens - waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) - dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling - verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse taaleisen, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:

J.I. van de Leuv

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:

CIBG-20201324

Bijlagen

Uw aanvraag

9 april 2020

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en het
kenmerk van deze brief.*

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report SL52025257751401TX **Date: June 02, 2020** **Page 1 of 9**
ZILINGO PTE LTD
20 BENDEMEER#03-12 SINGAPORE

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

Sample Description : (A-E)Medical Disposable Protective Coverall
Sample Color : (A)White; (B)White; (C)White; (D)White; (E)White
Order No. : MEA0420PDS039
Manufacturer : Zhejiang Huafu Medical Equipment Co.,Ltd
Country of Destination : India

Proposed Care Instruction : -

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : May 15, 2020
Testing Period : May 20, 2020 - Jun 02, 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 Report SL52025257751401TX **Date: June 02, 2020** **Page 2 of 9**

Test Result

Resistance to Penetration by Blood under Hydrostatic Pressure
(ISO 16603:2014, Procedure D)

Sample (A Fabric)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	0.44	0.46	0.46	0.46
Weight (g/m ²)	100	100	100	100
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass

Sample (A Seam)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	1.58	1.60	1.60	1.60
Weight (g/m ²)	130	130	130	130
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass



Test Report SL52025257751401TX **Date: June 02, 2020** **Page 3 of 9**

Sample (B Fabric)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	0.40	0.40	0.38	0.40
Weight (g/m ²)	90	90	90	90
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass

Sample (B Seam)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	1.52	1.50	1.52	1.52
Weight (g/m ²)	120	130	120	120
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass

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Member of the SGS Group (SGS SA)

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

Sara Guo

Sara Guo (Account Executive)



Test Report SL52025257751401TX **Date: June 02, 2020** **Page 4 of 9**

Sample (C Fabric)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	0.44	0.44	0.46	0.44
Weight (g/m ²)	80	80	80	80
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass

Sample (C Seam)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	1.50	1.56	1.54	1.54
Weight (g/m ²)	120	120	120	120
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass



Test Report SL52025257751401TX **Date: June 02, 2020** **Page 5 of 9**

Sample (D Fabric)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	0.40	0.42	0.40	0.40
Weight (g/m ²)	90	100	100	100
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass

Sample (D Seam)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	1.56	1.58	1.56	1.56
Weight (g/m ²)	130	130	130	130
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	1.75 kPa for 5 min	3.5 kPa for 5 min
Pass	Pass	Pass
Pass	Pass	Pass
Pass	Pass	Pass

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Sample (E Fabric)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	0.46	0.44	0.46	0.46
Weight (g/m ²)	100	90	100	100
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	Pass	Pass	Pass
1.75 kPa for 5 min	Pass	Pass	Pass
3.5 kPa for 5 min	Pass	Pass	Pass

Sample (E Seam)

Specimen	1#	2#	3#	Ave.
Thickness(mm)	1.54	1.52	1.52	1.52
Weight (g/m ²)	130	130	130	130
Observation on viewing side	1#	2#	3#	

Procedure D

0 kPa for 5 min	Pass	Pass	Pass
1.75 kPa for 5 min	Pass	Pass	Pass
3.5 kPa for 5 min	Pass	Pass	Pass

Remark : Pass- No penetration on viewing side, Fail- Penetration on viewing side

Sample Photo

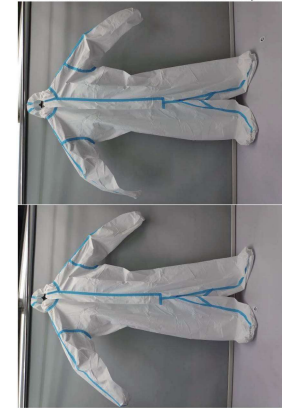



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The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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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

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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 		<ul style="list-style-type: none"> Manufacturer Manufacturer Manufacturer Manufacturer Manufacturer

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

CERTIFICATE

CERTIFICATE



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Establishment Registration & Device Listing

1 result found for Establishment Registration or FEI Number : 3014720527

Establishment Name	Registration Number	Current Registration Yr
ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD. CHINA	3014720527	2020
Depressor, Tongue, Non-Surgical - Tongue Depressor		Manufacturer
Non-Surgical Isolation Gown - Coverall		Manufacturer
Set, Administration, Intravascular - Infusion Set		Manufacturer
Dispenser, Liquid Medication - Oral Syringe		Manufacturer
Mask, Scavenging - Disposable Face Mask; Medical Mask		Manufacturer
Shield, Eye, Ophthalmic (Including Sunlamp Protective Eyewear And Post-Mydriatic Eyewear) - Goggle		Manufacturer
Accessory, Surgical Apparel - Disposable Glove; Face Shield; KN95		Manufacturer
Cap, Surgical - Bouffant Caps		Manufacturer
Cover, Shoe, Operating-Room - Disposable Shoe Covers		Manufacturer

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机构注册和设备清单

找到1个机构注册或FEI号的结果: 3014720527

机构名称	注册号码	当前注册年份
浙江华福医用器材有限公司 中国	3014720527	2020年
压舌器, 非手术舌头-压舌板		制造商
非手术隔离服-连体衣		制造商
套, 给药, 血管内-输液器		制造商
分配器, 液体药物-口服注射器		制造商
口罩, 清除-一次性口罩; 医用口罩		制造商
防护罩, 眼睛, 眼科 (包括日光防护眼镜和散瞳后眼镜) -Goggle		制造商
附件, 外科服装-一次性手套; 面罩; KN95		制造商
手术帽-蓬松帽		制造商
鞋套, 手术室-一次性鞋套		制造商

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U.S. Department of Health & Human Services

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合格证 QUALIFIED CERTIFICATE

产品名称: 医用一次性防护服
Product name: Disposable Medical Protective Clothing
规格型号 Specification: 无菌型
检验工号 Checker NO: 08
生产批号 LOT NO: 200520
生产日期 MFG DATE: 2020-05-20
使用期限 PERIOD OF USE: 6个月 / 6 Months
执行标准 Standard: GB19082-2009 (Clause 4.1, 4.4, 4.5, 4.7, 4.9, 4.12.2)

主要成分 Ingredient: 65%PP聚酯纤维、35%透气膜
注意事项 Precautions:

1. 产品为一次性使用, 禁止重复使用。
The product is single use only and is not allowed to be reused.
2. 使用前应检查包装完整性, 如发现包装破损, 严禁使用。
The integrity of the packaging should be checked before use, it is strictly prohibited to use if the packaging is broken.
3. 产品经辐照灭菌, 应无菌。
Products are sterilized by irradiation and is sterile.
4. 建议使用时间不超过12小时。
It is recommended that the use time not exceed 12 hours.
5. 被患者血液、体液、污物污染时, 应及时更换。
When contaminated with blood, body fluids and dirt, it should be replaced in a timely manner.
6. 产品使用后按照《医疗废物管理条例》的要求处理。
Products should be disposed of in accordance with the requirements of the Medical Waste Management Ordinance.

7. 没有经过灭菌处理的不能在无菌要求的环境下使用。
Without sterilization, it cannot be used in the environment required by sterile.
 8. 产品阻燃性未经过验证。
The flame retardant properties of the product have not been verified.
 9. 防护服只能在规定的区域内穿脱。
Protective clothing is only allowed to be put on and take off within the specified area.
 10. 穿前应检查防护服有无破损; 穿时勿使衣袖及面部及衣领。发现有渗漏或破损应及时更换; 脱时应注意避免污染。
Check the protective clothing for damage before wearing; do not let the sleeve touch the face and collar when wearing. If leakage or breakage is found, it should be replaced in time; take off the protective clothing carefully to avoid contamination.
- 包装规格 Packing specification: 1件/包
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生产企业许可证: 浙食药监械生产许20100281号

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OUTER PACKING 外箱包装

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40件/箱 40PCS/CTN
毛重: 12Kgs GW:12kgs
净重: 10.5kgs NW:10.5kgs

Carton size:60X40X40cm



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