

医用一次性防护服  
Disposable Protective Suit

浙江丑鸭实业有限公司、温州珍瑾服装有限公司  
Zhejiang Ugly Duck Industrial Co.,Ltd. / Wenzhou Zhnejin Clothing Co.,Ltd.

产品信息  
Product Information

产品名称 Product Name	医用一次性防护服 Disposable Protective Suit
产品规格 Product Specification	连身式带帽拉链形 One-piece style with hood and zipper
产品备案号 Product Record No.	浙温械备20200006 ZHEJIANG WENZHOU MACHINERY EQUIPMENT 20200006
产品标准 Product Standard	GB 19082-2009 《医用一次性防护服技术要求》 GB 19082-2009 Technical requirements for medical disposable protective suits
产品描述 Product Description	采用非织造布为主要原料，经裁剪、缝纫制成。非无菌提供，一样性使用。 Made of non-woven fabric after cutting and stitching, non-sterile and disposable.
产品组成 Construction	采用高质量SMMSS抗静电拒水材料缝制而成 It is made of high-quaity, anti-static and waterproof SMMSS material by stitching.
产品用途 Product Function	用于医疗机构门诊、病房、检验室、外勤、社区、公安等作普通隔离 Used for general quarantine in medical institutions, clinics, wards, test room, outside offices, communities, etc.

产品图片  
Product Information



产品包装信息  
Product Package Info



包装方式  
Packing Ways

单件袋装，20件入一箱  
1set in 1 polybag, and 20sets in one master carton.

箱规、重量  
Carton Meas/weight

58\*38\*28cm  
5.5kgs

产品证书  
Product Certificates

第一类医疗器械生产备案凭证

备案编号：浙温食药监械生产备20200003号

企业名称	浙江丑鸭实业有限公司		
住所	浙江省温州瓯海区东方南路2号		
生产场所	浙江省温州瓯海区东方南路2号		
法定代表人	潘跃	企业负责人	潘跃
生产范围	I类:14-14-医护人员防护用品,		
生产产品 列表	产品名称	产品备案号	备注
	隔离衣	浙温械备20200006号	应急产品
	***		

备案部门（公章）温州市市场监督管理局

备案日期：2020年02月11日



CERTIFICATE

ZERTIFIKAT

認證證書

CERTIFICATE

ZERTIFIKAT



## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that

**ZHEJIANG UGLY DUCK INDUSTRY CO., LTD**

**2 south dongfang road Wenzhou, Zhejiang, 325000, CHINA**

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

U.S. Agent for FDA  
Communications:

SUNGO TECHNICAL SERVICE INC.  
6050 W EASTWOOD AVE APT 201, CHICAGO,  
ILLINOIS 60630, USA  
Telephone: +1-855-957-7779 / E-mail: [sungo-group@yahoo.com](mailto:sungo-group@yahoo.com)

**Owner/Operator Number: 10063206**

**Device Listing#: See annex**

Listing No	Code	Device Name
D375662	LYU	ACCESSORY, SURGICAL APPAREL (protective mask)
D375663	OEA	Non-surgical isolation gown (Protective Coverall)

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.



Executive Director  
Issued: Mar. 19 2020  
Cert. No. 200705060918  
Expiration Date: Dec. 31 2020





## CE Documentation Review



No. 0B200319.ZUDPUS84

**Holder:** Zhejiang Ugly Duck Industry Co., Ltd.  
No. 2 Dongfang South Road, Ouhai District, Wenzhou  
City, Zhejiang Province, China

**Review goal:** Verification of the presence of the Technical  
File in regards of the Medical Devices Directive  
93/42/EEC Annex VII

**Product:** Medical protective clothing (**no sterile**)  
**Model(s):** 2020313

**Classification:** Class I (no sterile)  
(accordingly to the Manufacturer's declaration)

**Review output:** We attest that a Technical File in reference to the Directive  
93/42/EEC is in place for the CE Marking process.  
The manufacturer is responsible for the CE Marking process,  
and not exempted to carry out all necessary compliance  
activities. 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:** 19 March 2020

**Expiry date:** 18 March 2025

Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni

**Ente Certificazione Macchine**

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# Shaoxing Testing Institute of Quality and Technical Supervision

## Test Report

Report No: (2020) FHB00362

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Sample name	Protective suit	n Test category	Commissioned inspection (B)
Sample No	(2020) FHB 00362	Brand	UGLY DUCK
Specification	One-piece	Sample grade	/
Sample quantity	5 (of which:/)	Sample batch	/
Consignor	Zhejiang UGLY DUCK Industry Co., Ltd.	Consignor add	3/F, Jade Duck Industry, No. 2 East South Road, Ouhai District, Wenzhou City, Zhejiang Province
Manufacturer	/	Manufacturer add	/
Inspected unit	/	Inspected unit add	/
Sampling unit	/	Sampling add	/
Sampling date	/	Producing date/Batch	/
Sampling/Sending Samples staff	Yu Ye	Samples Arrival date	March 2 2020
Testing date	March 2, 2020 to March 3, 2020	Testing add	Our Academy
Sample (Sealing) state	White protective suit		
Test and Determine standards	GB 19082-2009 <i>Technical requirements for medical disposable protective suits</i>		
Test Item (s)	See next page for details		
Testing Apparatuses	Automatic filtration efficiency tester, steel ruler, digital seepage tester, universal material tester, etc.		
Environmental conditions	Temperature:/°C relative humidity:/% barometric pressure:/kPa wind speed:/m/s		
Test conclusion Test Conclusion	The inspection items of the samples tested meet the requirements of the standards.  Stamp Date: March 4, 2020		
Remarks Note	/		



Approver: 寿康圣

Review by: 池江琴

Compiled by: 傅珊



## 绍兴市质量技术监督检测院

Shaoxing Testing Institute of Quality and Technical Supervision

## 检验报告

## Test Report

报告编号Report No: (2020)FHB00362

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样品名称 Sample name	防护隔离衣	检验类别 Test category	委托检验 (B)
样品编号 Sample No	(2020)FHB00362	商标 Brand	UGLY DUCK
型号规格 Specification	连体衣	样品等级 Sample grade	/
样品数量 Sample quantity	5件(其中备样: /)	样品基数 Sample batch	/
委托单位 Consignor	浙江丑鸭实业有限公司	委托单位地址 Consignor add	浙江省温州市瓯海区东方南路2号丑鸭实业3楼
生产单位 Manufacturer	/	生产单位地址 Manufacturer add	/
受检单位 Inspected unit	/	受检单位地址 Inspected unit add	/
抽样单位 Sampling unit	/	抽样地点 Sampling add	/
抽样日期 Sampling date	/	生产日期/批号 Producing date/Batch	/
抽样/送样人员 Sampling/ Sending Samples staff	余也	到样日期 Samples Arrival date	2020年03月02日
检验日期 Testing date	2020年03月02日~2020年03月03日	检验地点 Testing add	本院
样品(封样)状态描述 Sample(Sealing) state	白色隔离衣		
检验和判定依据 Test and Determine standards	GB 19082-2009《医用一次性防护服技术要求》		
检验项目 Test Item(s)	详见下页		
主要仪器设备 Testing Apparatuses	自动过滤效率测试仪、钢直尺、数字式渗水性测定仪、万能材料试验机		
环境条件 Environmental conditions	温度: /℃ 相对湿度: % 气压: /kPa 风速: /m/s		
检验结论 Test Conclusion	所检样品, 其检验项目均符合标准要求。 (检验专用章 签发日期:		
备注 Note	/		



批准 Approver:

寿康圣

审核 Review by:

池江琴

编制 Compiled by:

傅琪