



防护隔离衣

坚决打赢疫情防御狙击战

防护隔离衣

备案号：浙温械备20200006
I类：14-14医护人员防护用品



防护隔离衣

连体式隔离衣/男女同款

- ✓ 医用级面料
- ✓ 防水防透湿
- ✓ 无孔微透气
- ✓ 三层防护更安全



防护服价格



有胶条68元

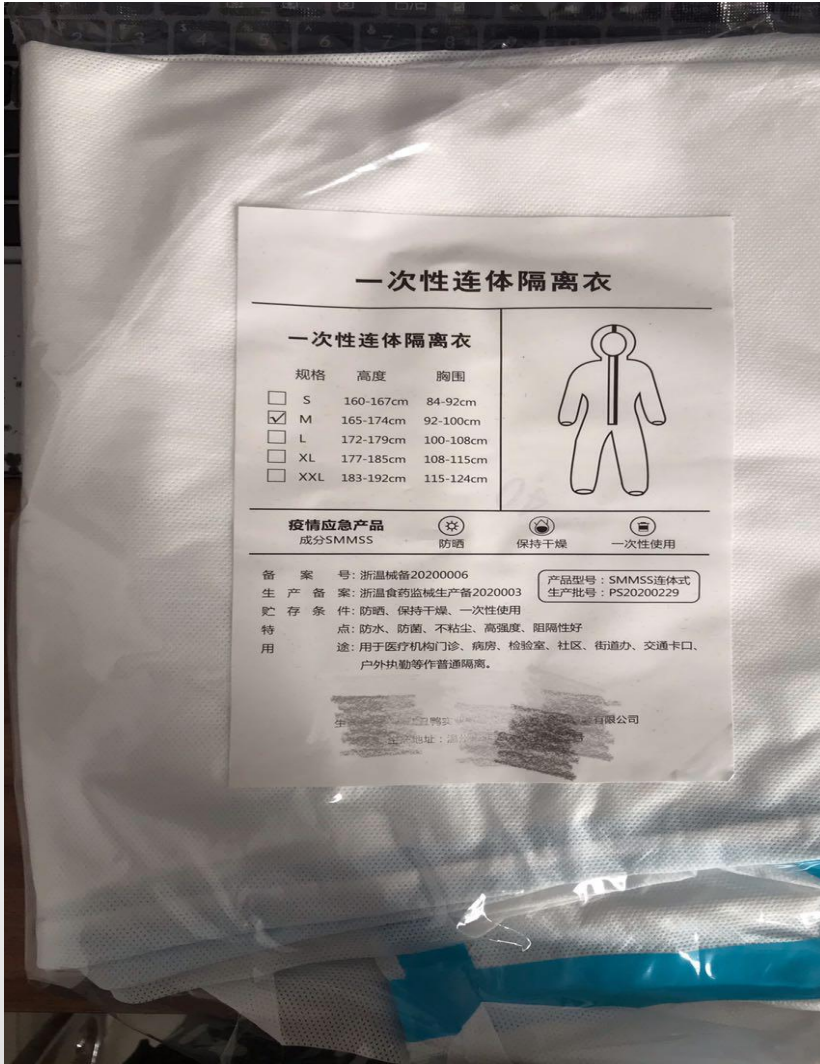


无胶条41元

I	J	K	L
码子	单件重量	备注	贴条重量
XL	233G	连包装袋贴纸	
L	225G		
M	215G		

A	B	C	D
尺码	单件（重量）	单箱（重量）	单箱规格
M	205. 6G	5. 35KG	53*38*27
L	216G	5. 55KG	
XL	224. 8G	5. 65KG	
XXL	236. 6G	5. 9KG	

产品实图



一箱20件

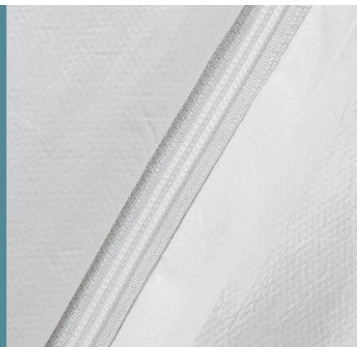


连帽设计

头部连帽设计
帽口松紧设计
有效阻隔灰尘和微生物

拉链设计

穿脱方便
简单大方



腰部松紧设计

腰部松紧设
使穿着更合体
满足不同身材穿着需求

防护服细节展示



连身基本尺寸

连身式基本尺寸

单位：厘米

尺码	规格	身长	胸围	袖长	袖口	脚口
S/09A	160	165	120	84	18	24
M/11A	165	169	125	86	18	24
L/13A	170	173	130	90	18	24
XL/15A	175	178	135	93	18	24
XXL/17A	180	181	140	96	18	24
XXXL/17B	185	188	145	99	18	24
偏差	偏差	±2	±2	±2	±2	±2

生产车间展示



生产展示



Review Report - 審査報告-검토 보고서-Rapport d'Evaluation

Documentation Review



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

Expiry date: 18 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE



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: +1-855-957-3779 / E-mail: 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.

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营业执照

统一社会信用代码

91330300785660593F (1/1)

营业执照

(副本)

扫描二维码登录“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

浙江丑鸭实业有限公司

类型

有限责任公司(中外合资)

法定代表人

潘跃

经营范围

医疗器械、特种劳动防护用品、汽车用电机、控制器、车内饰品、服装、面料、皮革饰品的生产、销售；太阳能发电、销售电力；节能技术推广；自有房屋租赁，仓储服务（不含危险品）；服装设计、技术转让；企业管理与咨询服务；文化创意策划，会议策划；货物进出口，技术进出口；基础软件服务、应用软件服务；组织文化艺术交流活动（不含营业性演出）；承办展览展示活动。（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

捌佰万美元

成立日期

2006年09月13日

营业期限

2006年09月13日至2056年09月12日

住所

浙江省温州瓯海区东方南路2号

登记机关

2020年02月20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

第一类医疗器械备案凭证

浙江丑鸭实业有限公司:

根据相关法规要求,对你单位第一类医疗器械:隔离衣予以备案,备案号:浙温械备 20200006 号。

仅用于客户归档



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

仅用于客户归档





坚决打赢疫情防御狙击战