

产品照片 —— 医用一次性防护服



浙江省疫情防控重点企业
国务院联防联控机制医疗物资保障组成员单位



 国务院联防联控机制医疗物资保障组成员单位
浙江省疫情防控重点企业

医用防护服 一次性

 药监局备案

欧盟CE认证
美国FDA认证



浙械注准 单件独立包装

...

干净卫生
安全保障



资质证明 ——CE认证

Certificate – Сертификат –證明書 – Certificate – 證明書 – Certificate – 證明서 – توثيق – معايير

Certificate of Compliance

No. 00200311.ZLG0N17

Certificate's Holder:

ZHEJIANG LANTIAN GARMENT CO., LTD.
No. 295 Hongda Road, Xiaoshan Economic Technology Development Zone, Hangzhou

Certification ECM Mark:



Product: Disposable Protective Clothing (Isolation Gown)
Model(s): LTZY-0226

Verification to: Standard:
EN 14126:2003+AC:2004

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it.

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:



We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 11 March 2020

Chief Manager
Marco Marzulli



Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
+39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it



Certificate of Compliance

No. 00200312.ZLG0N80

Certificate's Holder:

ZHEJIANG LANTIAN GARMENT CO., LTD.
No. 295 Hongda Road, Xiaoshan Economic Technology Development Zone, Hangzhou

Certification ECM Mark:



Product: Disposable Mask
Model(s): LTZY-0228

Verification to: Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it.

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:



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Date of issue 12 March 2020

Chief Manager
Marco Marzulli



Expiry date 11 March 2025

Deputy Manager
Amanda Payne



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증명서 – Certificate – 證明書 – Certificate – 證明書 – Certificate – 證明서 – توثيق – معايير

资质证明 ——FDA认证



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企业简介



浙江蓝天制衣有限公司创立于2013年10月，注册资金30016万元，公司专注安全防护用品的生产销售，为世界500强提供职业工装、特种防护服定制服务，为全世界10万家企业、学校提供专业工装、特种防护服、校服解决方案，是中国职业装和劳动防护用品的生产基地、国家高新技术企业，连续在2013-2019年度名列“全国劳动防护生产企业五十强”前十位。

“抗击疫情●我们在行动”，2020年1月26日，公司积极响应政府号召复工复产防护服和口罩。公司新增一、二类医疗器械生产经营项目，2月11日，取得医用隔离衣生产备案；2月26日，取得一次性医用防护服生产许可证和产品注册证；3月22日，取得一次性使用医用口罩产品注册证。

Zhejiang Lantian clothing co., LTD. Set up in October 2013, the registered capital of 300.16 million yuan, the company focus on safety protective equipment production and sales, providing the world top 500 professional equipment, special protective clothing customization service, to 10 enterprises, schools all over the world to provide professional equipment, special protective clothing, school uniform solution, is to work and labor protection supplies production base in China, The national high and new technology enterprise, in 2013-2019 annual consecutive ranked the top of the “national labor protection enterprise” the top ten.

On January 26, 2020, the company responded to the government's call to resume production of protective clothing and Disposable masks. The company added a new category I and II medical equipment production and operation projects, February 11, obtained the medical isolation clothing production record; On February 26, obtained the production license and product registration certificate of disposable medical protective clothing; On March 22, the registration certificate of disposable surgical mask product was obtained.

防护服生产车间一角



口罩生产车间一角



口罩生产设备



Healthy For your protection

Used for barrier protection of medical institutions,
sickbeds, laboratories, etc



Test Room



Inpatient Ward



medical institution



Outpatient clinic

100% POLYPROPYLENE FIBER (NON WOVEN)
100% POLYPROPYLENE FIBER (WOVEN)

Strong filtration
**Breathable
non-woven fabric**



Heavy and durable
Good air permeability



Information

Blue sky makes clothes, unite with one heart

产品优势

+

PRODUCT
SDFHJSDHKJFS



健康防护
LANTING



独立包装
LANTING



阻隔性强
LANTING



高纤材质
LANTING



II类医用
LANTING



蓝挺品牌
LANTING

Name : Disposable protective clothing for medical use

Advantage: Moisture permeability, anti tearing, anti-static, anti penetration, virus barrier

Structure : Protective clothing consists of hooded top and trousers

Range : This product is applicable to provide barrier and protection for medical personnel to contact patients with potential infection during work

Specifications : 165、170、175、180、185

防护服-使用说明书

医用一次性防护服 DISPOSABLE PROTECTIVE CLOTHING FOR MEDICAL USE

浙江蓝天制衣有限公司
ZHEJIANG LANTIAN GARMENT CO.,LTD.



仅供防控疫情应急使用
For emergency use only

蓝挺
LANTING

【医疗器械生产许可证编号】浙食药监械生产许20201103号
Production License Number: 20201103
【产品注册证编号】浙械注准20202141027
Medical Device Registration Certificate Number: 20202141027

医用一次性防护服

Disposable protective clothing for medical use

【产品名称】医用一次性防护服

【型号规格】非无菌型 160、165、170、175、180、185

【适用范围】供临床医务人员在工作的接触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。

【产品使用的原材料及结构组成】产品为连体式，由连帽上衣、裤子组成。袖口、不带鞋套的脚踝口、鞋套口、帽子面部收口及腰部收口采用弹性收口。防护服主体部分由非织造布（无纺布）材料制成，密封胶条采用EVA材料制成，拉链采用尼龙拉链。

【产品的性能及执行标准情况】本产品执行GB 19082-2009《医用一次性防护服技术要求》标准，除4.8阻燃性能、4.11皮肤刺激性、4.12.2防臭、4.13环氧乙烷残留量外。

【使用方法】1. 取出一小包装并检查，如包装无破损也未超过有效期，则可撕开。2. 应遵循先穿下衣，再穿上衣，然后戴好帽子，最后拉上拉锁的顺序。3. 脱防护服时，先将拉链拉到底，向上揭拉帽子，使帽子脱离头部，脱帽子；由上向下脱边襟，污染面向里直至全部脱下后放入医疗废物袋内。

【禁 忌】材料过敏者禁用。

【注意事项以及其他需要警示或提示的内容】1. 产品为一次性使用，禁止重复使用。2. 使用前应检查包装完整性，如发现包装破损，严禁使用。3. 产品非无菌提供。4. 建议使用时间不超过12小时。5. 被患者血液、体液、污水污染时，应及时更换。6. 产品使用后按《医疗废物管理条例》的要求处

理。7. 没有经过灭菌处理的不能在有灭菌要求的环境下使用。8. 产品稳定性未经过验证。9. 防护服只限在规定的区域使用。10. 穿前应检查防护服有无破损；穿时勿使衣物接触面部及衣领。发现有渗漏或破损应及时更换；脱时应注意避免污染。

【储存、运输条件、方法】1. 产品应防止阳光直射和雨水淋湿，运输时应防止重压。2. 产品贮存不存在腐蚀性气体和通风良好的室内。3. 使用期限/生产批号/生产日期】使用期限自生产之日起不超过6个月。生产批号、生产日期见包装或合格证。

Product Name: Disposable protective clothing for medical use.

Type / Size: Non-sterile/160, 165, 170, 175, 180, 185

Scope of application: Protection of medical personnel are exposed to potentially infectious blood, body fluids, secretions while theyon the jobs.
Raw Materials of Products: The product is one piece suit, It consists of a hoodie and trousers. The main body of the protective clothing is made of nonwoven (non-woven) material. The sealing tape is made of EVA material and the zipper is made of nylon.

Product performance and performance standards: This product complies with GB 19082-2009 technical requirements for disposable protective clothing for medical use (except 4.8 flame retardant performance, 4.11 skin irritation, 4.12.2 residual ethylene oxide).

Scope of application: It is used for blocking and protecting the blood, body fluids and secretions of patients with potential infectivity that clinical medical personnel come into contact with while working.

Method of use: 1. Take out the package and check. If there is no damage and within the period of validity, please use. 2. Please wear pants at first, then wear clothes on top, the last wear the hat and pull the zipper.3. Take off the protective clothing, at first pull down the zipper, Pull your hat up, let the hat take off. The sleeves are rolled up from top to bottom. The pollution clothing is inside and Place in clinical waste bag.

Contraindication:It is forbidden for people who are allergic to materials.

Warning:1.The product is disposable. Don't reuse.2. Please check the packing before use, if there is have damage, please don't use.3.The product is non-sterile.4. No more than 12 hours is recommended.5.When the patient's blood, body fluids, sewage pollution, should be promptly replaced.6.After use, the product shall be disposed in accordance with the requirements of the clinical waste management ordinance.7.This product can't be used in a sterile environment.8.The flame retardancy of the product has not been verified.9.Protective clothing should only be worn and removed within the designated area.10. Please check before you wear. Do not let the sleeve touch the face and collar when wearing. If there have damage, please don't use. Take care to avoid contamination when taking them off.

Storage and transportation conditions and methods:1. Products should prevent direct sunlight and rain wet, transport should prevent stress. 2. Products should be stored in a well ventilated room with no corrosive gases.

Term of use/batch number of production/date of production : The term of use shall not exceed 6 months from the date of production. Production batch number, production date can be found in the packagequalification certificate..

【注册人、生产单位、售后服务单位】浙江蓝天制衣有限公司

【注册人住所、生产企业住所、生产地址】浙江省杭州市萧山区萧山经济技术开发区桥南区块鸿达路295号

【注册人/生产企业联系方式】电话：0571-22819999 传真：0571-22868068

Name of Manufacturer: Zhejiang Lantian Garment Co., Ltd

Address of Manufacturer: 295Hongda Road,Xiaoshan Economic Technology Development Zone,Hangzhou City, Zhejiang Province, China.

Contact office number : +86-0571-22819999

Contact Email: Lantinggarment@163.com



资质证明 —— 医疗器械生产许可证



国家食品药品监督管理总局制

资质证明 ——营业执照副本



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

资质证明 ——国务院联防联控防疫物资保障组重点企业

重点企业名单发布！国务院发文保障隔离衣、手术衣企业复工复产

关于请保障隔离衣、手术衣生产企业复工复产的通知

肺炎机制医疗保障发〔2020〕202号

各省、自治区、直辖市及计划单列市工业和信息化主管部门：

为做好重点防疫物资生产供应保障，请你们抓紧组织本地区隔离衣、手术衣企业尽快复工复产，协调帮助企业解决生产经营中遇到的困难和问题。现将拟作为防疫物资保供单位的重点企业名单（见附件）印发你们，请对名单内企业生产情况进行调查核实，并于2月14日16:00前将核实情况反馈工业和信息化部（消费品工业司）。

联系人：吴桐 68205661（传真）、13811326292

附 件：1.隔离衣重点生产企业名单

2.手术衣重点生产企业名单

附件 1：隔离衣重点生产企业名单

序号	企业名称
1	浙江蓝天制衣有限公司
2	上海通用模塑有限公司
3	浙江蓝天制衣有限公司
4	上海通用模塑有限公司
5	上海通用模塑有限公司
6	上海通用模塑有限公司
7	上海通用模塑有限公司
8	上海通用模塑有限公司
9	上海通用模塑有限公司
10	上海通用模塑有限公司

国务院应对新型冠状病毒肺炎疫情
联防联控机制医疗物资保障组

2020年2月13日

资质证明 ——浙江省参与防控疫情重点企业

2020年2月2日

序号	企业名称	企业类型	产品种类	市县	企业联系人	联系人电话	报送单位
31	杭州电化集团有限公司	医用物品生产企业	消毒液	钱塘新区	蒋长城	13757171186	省发改委
32	泰尔茂医疗产品(杭州)有限公司	医用物品生产企业	测体温仪	钱塘新区	张炎	13819191628	省发改委
33	杭州巨星钢盾工具有限公司	医用物品生产企业	口罩	江干区	毛彬峰	13600543303	省发改委
34	杭州蓝天工业劳动保护用品厂	医用物品生产企业	口罩	江干区	朱	13958119066	省发改委
35	浙江蓝天制衣有限公司	医用物品生产企业	防护服	萧山区	郑志恩	13905813068	省发改委
36	杭州惠康医疗器械有限公司	医用物品生产企业	口罩	萧山区	莫关根	13506717872	省发改委
37	杭州昱鼎生物科技有限公司	医用物品生产企业	其他应急物资	萧山区	李幼祥	15268503818	省发改委
38	杭州传化日用品有限公司	医用物品生产企业	消毒液	萧山区	莫海滨	13588279049	省发改委
39	浙江永辉超市有限公司	销售型企业	生活必需品	杭州	赵斌	15840241919	省商务厅
40	祖名豆制品股份有限公司	销售型企业	生活必需品	杭州	高峰	15857116777	省商务厅
41	温州文成县南联超市有限公司	销售型企业	生活必需品	温州	郑建初	13868691388	省商务厅

资质证明 ——关于要求应急生产非医用防护服的函

杭州市萧山区应急管理局

关于要求应急生产非医用防护服的函

浙江蓝天制衣有限公司：

当前防控新型冠状病毒肺炎疫情形势严峻，相关防护物资需求高度紧缺。鉴于贵单位为专业特种劳动防护服生产企业，在2003年非典时期曾生产非医疗级的防护服，有较为丰富的生产经验，以及相关防护面料能达到防水、防撕裂、防尘、透气透湿的基本要求，根据萧山区防控指挥部指示，特要求贵单位迅速组织人员，生产一次性非医用防护服，供相关部门、单位使用。



资质证明 —— 医疗器械产品出口销售证明

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号: 浙杭食药监械出 20200196 号
Certificate NO.: Zhejiang Food and Drug Administration Medical Device Export Sales Certificate No. 20200196

产品名称: 医用一次性防护服等产品, 见附件 (共 1 页)
Product(s): Medical disposable protective clothing, etc. See Attachment
(1 Page)

规格型号: 见附件 (共 1 页)
Model: See Attachment (1 Page)

产品注册或备案凭证号: 见附件 (共 1 页)
Registration certificate(s): See Attachment (1 Page)

生产企业: 浙江蓝天制衣有限公司
Manufacturer: Zhejiang Lantian Garment Co., Ltd.

生产企业住所: 浙江省杭州市萧山区萧山经济技术开发区桥南区块鸿达路 295 号
Address of manufacturer: 295 Hongda Road, Qiaonan Block, Xiaoshan Economic and Technological Development Zone, Xiaoshan District, Hangzhou City, Zhejiang Province, China

生产许可或备案凭证号: 浙食药械生产许 20201103 号
Manufacturing License(s): Zhejiang Food and Drug Administration Medical Device Production License No. 20201103

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制, 出口医疗器械的企业应当保证其出口的医疗器械符合进口国(地区)的要求。
This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country(region).

证明有效日期至: 2020 年 08 月 26 日
This certification valid until: 2020/08/26

备注: /
Remark: /



附件

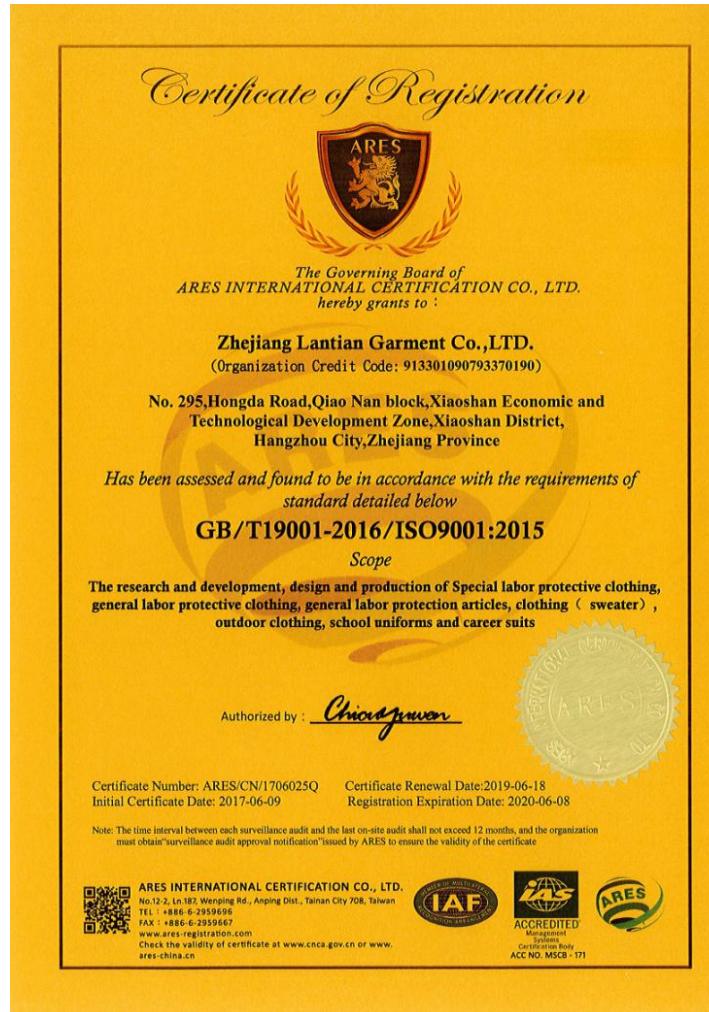
ATTACHMENT

证书编号: 浙杭食药监械出 20200196 号
Certificate NO.: Zhejiang Food and Drug Administration Medical Device Export Sales Certificate No. 20200196

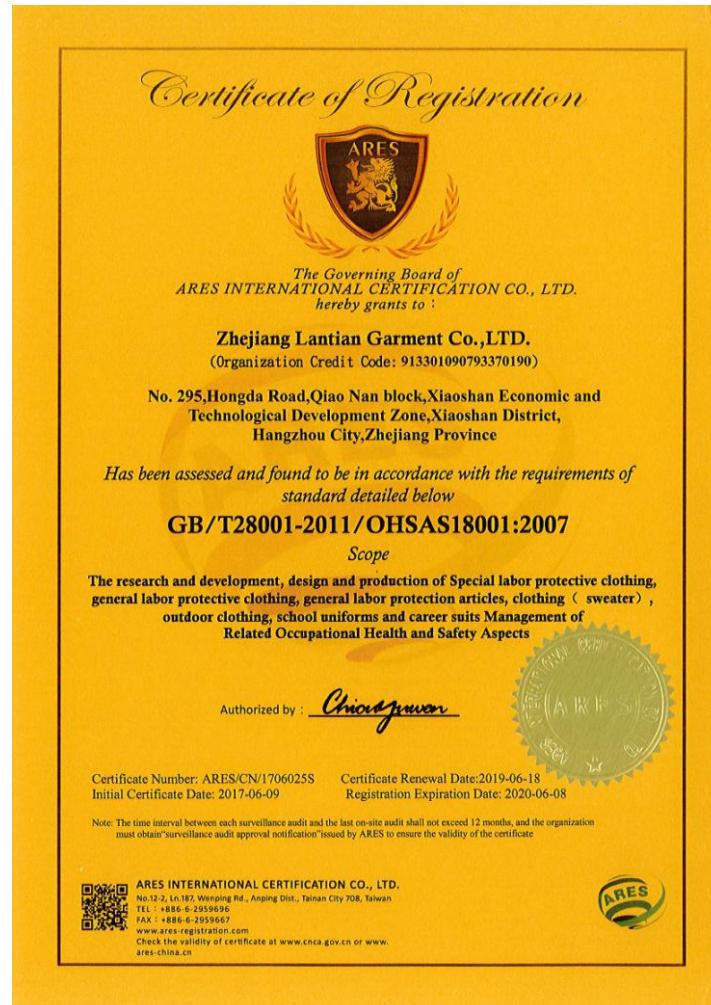
浙江省药品监督管理局
共 1 页 第 1 页
Page 1 of 1 Page

序号 SN	产品名称 Product(s)	规格型号 Model	医疗器械产品注册证号 Registration certificate(s)
1	医用一次性防护服 Disposable protective clothing for medical use	非无菌型 165、170、175、180、185 Non sterile 165、170、175、180、185	浙械注准 20202141027 Zhejiang Province mechanical remark No.20202141027
2	隔离衣 Isolation gown	S、M、L、XL、XXL、XXXL S、M、L、XL、XXL、XXXL	浙械械备 20200054 号 Hangzhou, Zhejiang Province mechanical remark No.20200054
空白 Blank	空白 Blank	空白 Blank	空白 Blank

资质证明 ——ISO/T19001-2016质量管理体系



资质证明 —— OHSA18001:2007职业健康安全管理体系



资质证明 ——ISO14001:2015环管理体系

