

永霏<sup>TM</sup>

# 医疗器械类产品手册

Introduction to Medical Devices of Yourfield<sup>TM</sup>



service phone number:400-6800181  
sale number:0731-55881181  
Website:www.yourfield.cn  
Adress: Building A2, Innovation Park, No.9 Shuangyong Road,  
High-tech Zone, Xiangtan City, Hunan Province

**服务热线:**400-6800181  
**销售热线:**0731-55881181  
**网址:**www.yourfield.cn  
**地址:**湖南省湘潭市高新区双拥路9号创新创业园A2栋

**湖南永霏特种防护用品有限公司**  
Hunan Yourfield Special Protective Equipment Co., Ltd.



# WELCOME

永霏集团是一家集特种服装研发生产、行业安全技术培训、企业安全解决方案为一体的集团公司。旗下有湖南永霏特种防护用品有限公司、湖南永霏医疗器械有限公司、湘潭市永霏安全科技有限公司等公司。

湖南永霏医疗器械有限公司是永霏集团独资的子公司，是在国家非常特殊的时期投资的。主要以医用防护服的研发、生产、销售为一体的专业化企业，不仅是湖南省内获得首张医疗器械类医用一次性防护服生产许可证的公司，而且还填补了省内医用一次性防护服生产的空白，响应了战略物资的储备。永霏秉持着“以品质求生存、以科技促发展、以人才塑企业”的核心理念，坚持自主创新。

公司从人文理念和呵护人类健康的角度，选择医用防护服为主打产品。它适应了国内医用防护服的市场需求，正确的选择了市场定位和产品定位，为公司的发展奠定了坚实的基础。并整合优势资源，力争为消费者提供更安全、更健康、更专业的防护产品。

永霏人满怀希望与激情，立志于打造驻扎人们心中的医用防护服。立足于安全健康产业，以全球化的视野，持续的创新和卓越的服务，为未来成为知名品牌而不懈努力。愿与大家一起为全人类的健康事业和社会的安定承担我们应有的责任。

我们同呼吸，共命运！

Yourfield Group is a group company integrating research & development and production of special clothing, industrial safety technology training and enterprise safety solutions. Its subsidiaries include Hunan Yourfield Special Protective Equipment Co., Ltd., Hunan Yourfield Medical Equipment Co., Ltd., Xiangtan Yourfield Safety Technology Co., Ltd., etc.

Hunan Yourfield Medical Equipment Co., Ltd., a wholly-owned subsidiary of Yourfield Group, is a specialized enterprise invested by the state during the special period, focusing on the research & development, production and sales of medical protective suits. It is not only the first company in Hunan province obtaining the production license for disposable medical protective suits, but also fills the gap in the production of disposable medical protective suits in Hunan province and responds to the reserve of strategic materials. Adhering to the core concept of "survival by quality, development by science and technology, and shaping enterprise by talents", Yourfield insists on independent innovation.

It chooses medical protective suits as the main product from the perspective of humanism idea and protecting human health. It adapts to the domestic market requirements for medical protective suits, correctly selects the market positioning and product positioning, and lays a solid foundation for its development. By integrating advantageous resources, it strives to provide consumers with safer, healthier and more professional protective products.

Yourfield people, full of hope and passion, are determined to produce medical protective suits that always stay in the hearts of people. Based on the safety and health industry, with a global vision, continuous innovation and excellent service, we will make unremitting efforts to become a well-known brand in the future. For the health of all mankind and the stability of our society, we are willing to undertake our due responsibilities together with all of you.

We breathe the same air and share the same fate!

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# 营业执照

(副本)

统一社会信用代码  
914303007431760827



名称 湖南永霖特种防护用品有限公司  
 类型 有限责任公司(自然人投资或控股)  
 法定代表人 李文辉

注册资本 壹亿壹仟肆佰叁拾叁万元整  
 成立日期 2002年11月07日  
 营业期限 长期

经营范围 劳保用品、医疗器械、编织袋、羽绒服、皮衣及其他服装的生产与销售(含网上销售); 阻燃服、屏蔽服、防静电服、焊工服、绝缘服、防辐射服、高压防静电服、防电弧服等特种服装、安全鞋、安全防护用品的研发、生产与销售(含网上销售); 安全工器具、仪器仪表、消防器材、服装加工设备及配件、纺织品、日用品、五金产品、橡胶制品及建筑材料、办公用品、洗涤用品及清洁用品、清洁设备的研发与销售(含网上销售); 企业管理咨询; 安全标识牌的加工与销售。(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)

住所 湘潭市高新区双拥路9号创新创业园A2栋401号



登记机关  
2020年2月25日

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。

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日通过国家企业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



统一社会信用代码  
914303007431760827

## 营业执照

(副本)



名称 湖南永霖特种防护用品有限公司  
 Hunan Yourfield Special Protective Equipment Co., Ltd.  
 类型 有限责任公司(自然人投资或控股)  
 Type Limited liability company (invested or controlled by natural person)  
 法定代表人 李文辉  
 Legal Representative Li Wenhui

注册资本 壹亿壹仟肆佰叁拾叁万元整  
 Registered Capital RMB one hundred and fourteen million one hundred and thirty thousand only  
 成立日期 2002年11月07日  
 Establishment Date November 07, 2002  
 营业期限 长期  
 Operation Term Long-term  
 住所 湘潭市高新区双拥路9号创新创业园A2栋401号  
 Address No.401, Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City

经营范围 劳保用品、医疗器械、编织袋、羽绒服、皮衣及其他服装的生产与销售(含网上销售); 阻燃服、屏蔽服、防静电服、焊工服、绝缘服、防辐射服、高压防静电服、防电弧服等特种服装、安全鞋、安全防护用品的研发、生产与销售(含网上销售); 安全工器具、仪器仪表、消防器材、服装加工设备及配件、纺织品、日用品、五金产品、橡胶制品及建筑材料、办公用品、洗涤用品及清洁用品、清洁设备的研发与销售(含网上销售); 企业管理咨询; 安全标识牌的加工与销售。(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)  
 Production and sales (excluding online sales) of labor protection articles, medical devices, woven bags, down jackets, leather garments and other clothing; Research, development, production and sales (including online sales) of special clothing such as flame retardant clothing, shielding clothing, acid and alkali resistant clothing, welder's clothing, insulating clothing, radiation resistant clothing, high voltage anti-static clothing, anti-static clothing, anti-ar clothing, safety shoes and safety rescue equipment; Research, development and sales (including online sales) of safety tools, instruments, fire fighting equipment, clothing processing equipment and accessories, textiles, daily necessities, hardware products, rubber products and building materials, office supplies, clothing, fabrics, washing supplies and cleaning supplies; cleaning equipment; Enterprise management consulting; Processing and sales of safety signs. (For the items that are subject to approval according to laws, the business activities shall be carried out only with approvals from relevant departments)



登记机关  
Registered by  
湘潭市市场监督管理局 (Seal)  
Xiangtan Administration for Market Regulation (Seal)  
2020年2月25日  
February 25, 2020

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>  
 Website for National Enterprise Credit Information Publicity System: <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  
 The annual report shall be annually declared at the customs by the market entity between January 1 and June 30 through the national credit publicity system.

国家市场监督管理总局监制  
 Supervised by the State Administration for Market Regulation



国家药品监督管理局制

医疗器械生产许可证  
Medical Device Production License

许可证编号: 湘食药监械生产许 20200010 号  
License No.: XSYJXSCX 20200010

<b>企业名称:</b> <b>Enterprise Name:</b>	湖南永霏特种防护用品有限公司 Hunan Yourfield Special Protective Equipment Co., Ltd.	<b>生产地址:</b> <b>Production Site:</b>	湖南省湘潭市高新区双拥路9号创新创业园A2栋、湖南湘乡经济开发区红仓大道001号、湖南省湘潭市岳塘区创业路9号、湖南省韶山市韶山乡平里村 Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province; No.001 Honglun Avenue, Xiangxiang Economic Development Zone, Hunan Province; No.9 Chuangye Road, Yuetang District, Xiangtan City, Hunan Province; Pingli Village, Shaoshan Town, Shaoshan City, Hunan Province
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<b>法定代表人:</b> <b>Legal Representative:</b>	李文辉 Li Wenhui	<b>生产范围:</b> <b>Production Scope:</b>	II类: 14-14 医护人员防护用品 Class II: 14-14 Protective Articles for Medical Staff
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<b>企业负责人:</b> <b>Head of Enterprises:</b>	李文辉 Li Wenhui
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<b>住所:</b> <b>Address:</b>	湖南省湘潭市高新区双拥路9号创新创业园A2栋 Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province	<b>发证部门:</b> <b>Issued by:</b>	湖南省药品监督管理局 Hunan Medical Products Administration 湖南省药品监督管理局 (seal) Hunan Medical Products Administration (Seal)
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<b>有效期限:</b> <b>Validity Term:</b>	至 2025 年 02 月 01 日 To February 1, 2025	<b>发证日期:</b> <b>Date of Issue:</b>	2020 年 02 月 10 日 February 10, 2020
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国家药品监督管理局制  
Prepared by National Medical Products Administration

二类医疗器械备案

2020/1/26

第二类医疗器械经营备案批件打印

第二类医疗器械经营备案凭证

备案编号：湘湘潭市药监械经营备20200036号

企业名称	湖南永霏特种防护用品有限公司
法定代表人	李文辉
企业负责人	李文辉
经营方式	批发
住所	湖南省湘潭市高新区双拥路9号创新创业园A2栋401号
经营场所	湖南省湘潭市高新区双拥路9号创新创业园A2栋401号
库房地址	湖南省湘潭市高新区双拥路9号创新创业园A2栋401号
经营范围(旧版)	6864;
经营范围(新版)	14;

备案部门(公章)  
备案日期: 2020-01-26



2020/1/26  
2020/1/26

第二类医疗器械经营备案批件打印

Class II Medical Devices Business Filing Document Printing

第二类医疗器械经营备案凭证  
Class II Medical Devices Business Filing Certificate

备案编号：湘湘潭市药监械经营备 20200036 号

Filing No.: XXTSYJXJYB 20200036

企业名称 Enterprise Name	湖南永霏特种防护用品有限公司 Hunan Yourfield Special Protective Equipment Co., Ltd.
法定代表人 Legal Representative	李文辉 Li Wenhui
企业负责人 Head of Enterprise	李文辉 Li Wenhui
经营方式 Business Type	批发 Sale by bulk
住所 Address	湖南省湘潭市高新区双拥路9号创新创业园A2栋401号 No.401, Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province
经营场所 Business Address	湖南省湘潭市高新区双拥路9号创新创业园A2栋401号 No.401, Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province
库房地址 Warehouse Address	湖南省湘潭市高新区双拥路9号创新创业园A2栋401号 No.401, Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province
经营范围(旧版) Business Scope (former)	6864;
经营范围(新版) Business Scope (current)	14;

备案部门(公章)  
Filing Department (official seal)

湘潭市市场监督管理局 (seal)  
Xiangtan Administration for Market Regulation (Seal)

备案日期: 2020-01-26  
Filing Date: 01-26-2020



## 国务院应对新型冠状病毒肺炎疫情影响联防联控机制(医疗物资保障组)

肺炎机制医疗保障发〔2020〕151号

### 关于增加国家临时收储重点生产企业的函

中国医药集团有限公司、江苏广达医材集团有限公司、石家庄际华三五零二职业装有限公司、北京依文服饰股份有限公司、北京邦维高科特种纺织品有限责任公司、**湖南永霏特种防护用品有限公司**：

根据《国务院办公厅关于组织做好疫情防控重点物资生产企业复工复产和调度安排工作的紧急通知》(国办发明电〔2020〕2号)要求，解决重点地区特别是武汉市防控物资紧急需求，国务院应对新型冠状病毒肺炎疫情影响联防联控机制医疗物资保障组负责对重点医疗应急防控物资实施统一管理、统一调运。为进一步提高重要物资保障能力，经研究决定如下事项。

一、自2月10日起，增加江苏广达医材集团有限公司、石家庄际华三五零二职业装有限公司、北京依文服饰股份有限公司、北京邦维高科特种纺织品有限责任公司和湖南永霏特种防护用品有限公司为医用防护服(国标)国家临时收储重点生产企业。

二、请中国医药集团有限公司与各生产企业加强沟通衔接，按照医疗物资保障组每日下发的紧急调运收储任务单的要求落实医用防护服(国标)调运收储任务。

联系人：

工业和信息化部运行监测协调局一级主任科员

电话：010-

医疗物资保障组：

工业和信息化部运行监测协调局副

工业和信息化部运行监测协调局外

电话：010-

国务院应对新型冠状病毒肺炎疫情影响联防联控机制医疗物资保障组

2020年2月10日

抄送：北京市人民政府，河北省人民政府，江苏省人民政府，湖南省人民政府。

医疗器械注册证(无菌型)

中华人民共和国医疗器械注册证

注册证编号：湘械注准20202140144

注册人名称	湖南永霏特种防护用品有限公司
注册人住所	湘潭市高新区双拥路9号创新创业园A2栋
生产地址	湖南湘乡经济开发区红仓大道001号和湘潭市高新区双拥路9号创新创业园A2栋
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：连身式（无菌型），规格：160（S），165（M），170（L），175（XL），180（XXL），185（XXXL）
结构及组成	医用一次性防护服由连帽上衣、裤子组成，为连身式结构。无菌提供。
适用范围	供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用。
附件	产品技术要求
其他内容	
备注	1. 该产品为应急审批注册，有效期为八个月；2. 该产品在延续/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局

批准日期：2020年02月04日

有效期至：2020年10月03日



Registration Certificate for Medical Device of People's Republic of China

Registration Certificate No.: XXZZ 20202140144

Registrant Name	Hunan Yourfield Special Protective Equipment Co., Ltd.
Registrant Address	Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City
Production Site	Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province
Agent Name	N/A
Agent Address	N/A
Product Name	Medical Disposable Protective Suit
Model/Specification	175(XL), 180(XXL), 185(XXXL) Model: Coverall (non-sterile), Specifications: 160(S), 165(M), 170(L), 175(XL), 180(XXL), 185(XXXL)
Structure/Composition	The medical disposable protective suit is of the coverall structure that consists of a hooded top and trousers. sterile.
Scope of Application	It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work.
Attachment	Product technical requirements
Other Contents	
Remarks	1. This product is approved and registered for emergency with a validity period of eight months. 2. In case of renewing/changing the registration of this product, information should be completed in accordance with the management requirements for medical device registration.

Approved by: Hunan Medical Products Administration

Approved on: February 4, 2020

Expiration date: October 03, 2020





医疗器械注册证(非无菌型)

中华人民共和国医疗器械注册证

注册证编号：湘械注准20202140142

注册人名称	湖南永霏特种防护用品有限公司
注册人住所	湘潭市高新区双拥路9号创新创业园A2栋
生产地址	湖南省湘潭市高新区双拥路9号创新创业园A2栋
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：连身式（非无菌型），规格：160（S），165（M），170（L），175（XL），180（XXL），185（XXXL）
结构及组成	医用一次性防护服由连帽上衣、裤子组成，为连身式结构。非无菌提供。
适用范围	供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用。
附件	产品技术要求
其他内容	
备注	1. 该产品属于应急审批注册，有效期为八个月；2. 该产品在延续注册/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局

批准日期：2020年02月01日

有效期至：2020年09月30日



Registration Certificate for Medical Device of People's Republic of China

Registration Certificate No.: XXZZ 20202140142

Registrant Name	Hunan Yourfield Special Protective Equipment Co., Ltd.
Registrant Address	Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City
Production Site	Building A2, Innovation Pioneer Park, No.9 Shuangyong Road, High-tech Zone, Xiangtan City, Hunan Province
Agent Name	N/A
Agent Address	N/A
Product Name	Medical Disposable Protective Suit
Model/Specification	175(XL), 180(XXL), 185(XXXL) Model: Coverall (non-sterile), Specifications: 160(S), 165(M), 170(L), 175(XL), 180(XXL), 185(XXXL)
Structure/Composition	The medical disposable protective suit is of the coverall structure that consists of a hooded top and trousers. Supplied in a non-sterile manner.
Scope of Application	It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work.
Attachment	Product technical requirements
Other Contents	
Remarks	1. This product is approved and registered for emergency with a validity period of eight months. 2. In case of renewing/changing the registration of this product, information should be completed in accordance with the management requirements for medical device registration.

Approved by: Hunan Medical Products Administration

Approved on: February 1, 2020

Expiration date: September 30, 2020



医疗器械注册证变更文件

中华人民共和国  
医疗器械注册变更文件

注册证编号:湘械注准20202140142

产品名称	医用一次性防护服
变更内容	<p>1. 变更适用范围: 适用范围由“供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用。”变更为“供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护用。不能用于隔离重症监护病区(房)等有严格微生物指标控制的场所。”</p> <p>2. 变更结构及组成: 结构及组成由“医用一次性防护服由连帽上衣、裤子组成, 为连身式结构。非无菌提供。”变更为“医用一次性防护服采用覆膜无纺布材料制成, 由连帽上衣、裤子组成, 为连身式结构。非无菌提供。”</p>
备注	本文件与“湘械注准20202140142”注册证共同使用。

审批部门:湖南省药品监督管理局

批准日期:2020年02月07日



Registration Certificate No.: XXZZ 20202140144

Product Name	Medical disposable protective suit
Content of Change	<p>1. Change in the scope of application: The scope of application is changed from "It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work." to "It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work, but it cannot be used in such places as isolating intensive care units (rooms) with the requirement for strict microbiological indicator control."</p> <p>2. Change in structure and composition: The structure and composition is changed from "The disposable medical protective suit is of coverall structure, consisting of hooded top and trousers, supplied in a non-sterile manner." to "The disposable medical protective suit is made of film-coated non-woven fabrics, consists of hooded top and trousers, and is of coverall structure, supplied in a non-sterile manner."</p>
Remarks	This document should be used together with the registration certificate numbered XXZZ 20202140142.

Approved by: Hunan Medical Products Administration

Approved on: February 7, 2020



中华人民共和国  
医疗器械注册变更文件

注册证编号:湘械注准20202140144

产品名称	医用一次性防护服(无菌型)
变更内容	<p>1. 变更产品名称:由“医用一次性防护服”变更为“医用一次性防护服(无菌型)”。</p> <p>2. 变更型号、规格:由“型号:连身式(无菌型),规格:160(S),165(M),170(L),175(XL),180(XXL),185(XXXL)”变更为“型号:连身式(无菌型),规格:160-I(S),165-I(M),170-I(L),175-I(XL),180-I(XXL),185-I(XXXL);160-II(S),165-II(M),170-II(L),175-II(XL),180-II(XXL),185-II(XXXL)”。</p> <p>3. 变更结构及组成:由“医用一次性防护服由连帽上衣、裤子组成,为连身式结构。无菌提供。”变更为“医用一次性防护服采用覆膜无纺布材料制成,为连身式结构。I型防护服由连帽上衣、裤子组成,II型防护服由连帽上衣、裤子、鞋套组成。无菌提供。”</p> <p>4. 变更产品技术要求:详见附表1。</p>
备注	本文件与“湘械注准20202140144”注册证共同使用。

审批部门:湖南省药品监督管理局

批准日期:2020年03月08日



The People's Republic of China  
Document for Change of Medical Device Registration Information

Registration Certificate No.: XXZZ 20202140144

Product Name	Disposable Emergency Medical Garment (sterile)
Content of Change	<p>1. Change in product name: from "disposable medical protective suit" to "disposable medical protective suit (sterile)".</p> <p>2. Change in type and specification: from "Type: coverall structure (sterile), specification: 160(S), 165(M), 170(L), 175(XL), 180(XXL), 185(XXXL)" to "Type: coverall structure (sterile), specification: 160-I(S), 165-I(M), 170-I(L), 175-I(XL), 180-I(XXL), 185-I(XXXL); 160-II(S), 165-II(M), 170-II(L), 175-II(XL), 180-II(XXL), 185-II(XXXL)."</p> <p>3. Change in structure and composition: from "The disposable medical protective suit is of coverall structure, consisting of hooded top and trousers, supplied in a sterile manner." to "The disposable medical protective suit is made of film-coated non-woven fabrics, and is of coverall structure. Type I protective suit consists of hooded top and trousers, and type II protective suit consists of hooded top, trousers and shoe covers, supplied in a sterile manner."</p> <p>4. Change in technical requirements of the product: See Attachment 1 for details.</p>
Remarks	This document should be used together with the registration certificate numbered XXZZ 20202140144.

Approved by: Hunan Medical Products Administration

Approved on: March 8, 2020



## 医疗器械注册证变更文件

中华人民共和国  
医疗器械注册变更文件

注册证编号:湘械注准20202140142

产品名称	医用一次性防护服（非无菌型）
变更内容	<p>1. 变更产品名称: 由“医用一次性防护服”变更为“医用一次性防护服（非无菌型）”。</p> <p>2. 变更型号、规格: 由“型号: 连身式（非无菌型），规格: 160（S），165（M），170（L），175（XL），180（XXL），185（XXXL）”变更为“型号: 连身式（非无菌型），规格: 160-I（S），165-I（M），170-I（L），175-I（XL），180-I（XXL），185-I（XXXL）；160-II（S），165-II（M），170-II（L），175-II（XL），180-II（XXL），185-II（XXXL）。”</p> <p>3. 变更结构及组成: 由“医用一次性防护服采用覆膜无纺布材料制成，由连帽上衣、裤子组成，为连身式结构。非无菌提供。”变更为“医用一次性防护服采用覆膜无纺布材料制成，为连身式结构。I型防护服由连帽上衣、裤子组成，II型防护服由连帽上衣、裤子、鞋套组成。非无菌提供。”</p> <p>4. 变更产品技术要求: 详见附表1。</p>
备注	本文件与“湘械注准20202140142”注册证共同使用。

审批部门:湖南省药品监督管理局

批准日期:2020年03月08日



湖南永霖特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO. LTD

仅供存档 严禁商用 违法必究

The People's Republic of China

Document for Change of Medical Device Registration Information

Registration Certificate No.: XXZZ 20202140144

Product Name	Disposable Emergency Medical Garment (Not-sterile)
Content of Change	<p>1. Change in product name: from "disposable medical protective suit" to "disposable medical protective suit (non-sterile)."</p> <p>2. Change in type and specification: from "Type: coverall structure (non-sterile), specification: 160(S), 165(M), 170(L), 175(XL), 180(XXL), 185(XXXL)" to "Type: coverall structure (non-sterile), specification: 160-I(S), 165-I(M), 170-I(L), 175-I(XL), 180-I(XXL), 185-I(XXXL); 160-II(S), 165-II(M), 170-II(L), 175-II(XL), 180-II(XXL), 185-II(XXXL)."</p> <p>3. Change in structure and composition: from "The disposable medical protective suit is made of film-coated non-woven fabrics, consists of hooded top and trousers, and is of coverall structure, supplied in a non-sterile manner." to "The disposable medical protective suit is made of film-coated non-woven fabrics, and is of coverall structure. Type I protective suit consists of hooded top and trousers, and type II protective suit consists of hooded top, trousers and shoe covers, supplied in a non-sterile manner."</p> <p>4. Change in technical requirements of the product: See Attachment 1 for details.</p>
Remarks	This document should be used together with the registration certificate numbered XXZZ 20202140142.

Approved by: Hunan Medical Products Administration

Approved on: March 8, 2020





# 检验检测报告

## Test Report

(2020) WSZ FHL 第 0132 号

产品名称 医用一次性防护服  
 Product Name  
 委托单位 湖南永霏特种防护用品有限公司  
 Applicant  
 生产单位 \_\_\_\_\_  
 Manufacturer  
 检验检测类别 委托检验  
 Test Type

江苏国健检测技术有限公司  
 Jiangsu Guojian Testing Technology Co.,Ltd

# Test Report

(2020) WSZ FHL NO.0132

Product Name Disposable Emergency Medical Garment  
 Applicant Hunan Yourfield special protective equipment limited-liability company  
 Manufacturer \_\_\_\_\_  
 Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co.,Ltd

检验专用章

# 检验检测报告

## Test Report

[2020] WSZ FHL 第 0132 号

共 3 页 第 1 页

产品名称 Product name	医用一次性防护服	规格型号 Specification	—
		商 标 Brand	—
委托单位/地址/联系电话 Applicant/Add/Tel	湖南永霏特种防护用品有限公司/湘潭市高新区双拥路9号创新创业园A2栋401号/15200384607		
生产单位/地址/联系电话 Manufacturer/Add/Tel	—/—/—		
样品等级 Sample grade	—	样品编号 Sample number	GW 0132-2020
样品数量 Sample quantity	3 套	样品接收日期 Receiving date of sample	2020年02月02日
检验检测类别 Test type	委托检验	货号/批号/款号 Article number/Batch number/Style number	—
检验检测日期 Test date	2020/02/02~2020/02/17	检验检测地点 Test site	本公司检验室
样品状态 Sample state	符合检验检测要求		
检验检测依据 Test standard(s)	GB 19082-2009 《医用一次性防护服技术要求》		
检验检测项目 Test items	抗渗水性、透湿量、抗合成血液穿透性、表面抗湿性、断裂强力、断裂伸长率、过滤效率、阻燃性能、静电衰减性能、抗静电性、微生物指标、外观、结构、号型规格、环氧乙烷残留量		
检验检测结论 Test conclusion	样品经检验，所检项目符合 GB 19082-2009 标准规定的要求，具体检验结果详见第 2-3 页。 签发日期 2020 年 2 月 17 日		
备 注 Note	样品信息由委托方提供，本报告仅对来样负责 报告有效期为 1 年		

批准:

审核:

主检:



# Test Report

[2020] WSZ FHL NO.0132

Page 1 of 3

Product name	Disposable Emergency Medical Garment	Specification	—
		Brand	—
Applicant/Add /Tel	Hunan Yourfield special protective equipment limited-liability company /Building A2, No.9, Innovation Park, Shuangyong Road, High-Tech District, Xiangtan City, Hunan Province, P.R. China/15200384607		
Manufacturer/ Add/Tel	—/—/—		
Sample grade	—	Sample number	GW0132-2020
Sample quantity	3	Receiving date of sample	2020.02.02
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	2020/02/02~2020/02/17	Test site	Testing room
Sample state	Meet the requirements		
Test standard(s)	GB 19082-2009 《Technical requirements for disposable protective clothing for medical use》		
Test items	Water permeability, Moisture permeability, Synthetic blood penetration resistance, Surface moisture resistance, Breaking strength, Breaking elongation, Filtering efficiency, Antistatic, flame retardancy, Microorganism, Electrostatic attenuation, Oxirane residue, Appearance, Structure, Model Specification (One-piece pose)		
Test conclusion	The sample upon examination, the projects meet the requirements of the GB 19082-2009 standard, the specific test results see page 2-3.		
Note	The sample information is provided by Applicant. This report is only responsible for samples received.		

Approver:

Reviewer:

Main surveyor:



Issue date: 2020.3.16

检验检测技术有限公司

湖南永霏特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO. LTD  
仅供存档 严禁商用 违法必究

永霏

## 检验检测结果

### Test Result

[2020] WSZ FHL 第 0132 号

共 3 页 第 2 页

序号 Number	检验检测项目 Test item	单位 Unit	技术要求 Technical requirement	检验检测结果 Test result	单项 评价 Single item decision
1	抗渗水性	kPa	$\geq 1.67$	21.0	合格
2	透湿量	$g/(m^2 \cdot d)$	$\geq 2500$	6410	合格
3	抗合成血液穿透性	—	$\geq 2$ 级	6 级	合格
4	表面抗湿性	—	$\geq 3$ 级	1# 4 级	合格
				2# 4 级	
				3# 4 级	
5	断裂强力	N	$\geq 45$	82	合格
				49	
6	断裂伸长率	—	$\geq 15\%$	65%	合格
				74%	
7	过滤效率	—	$\geq 70\%$	99.8%	合格
				99.7%	
				99.8%	
				99.8%	
				99.9%	
				99.8%	
8	阻燃性能	mm	$\leq 200$	纵向 179	合格
				横向 194	
				纵向 0.9	
				横向 0.6	
				纵向 0.5	
				横向 0.4	
9	微生物指标	—	包装上标志有“灭菌”或“无菌”字样或图示的防护服应无菌。	无菌	合格

## Test Result

[2020] WSZ FHL NO.0132

Page 2 of 3

Number	Test item	Unit	Technical requirements	Test Result	Single Item decision
1	Water permeability	kPa	$\geq 1.67$	21.0	Qualified
2	Moisture permeability	$g/(m^2 \cdot d)$	$\geq 2500$	6410	Qualified
3	Synthetic blood penetration resistance	—	$\geq$ Level 2	Level 6	Qualified
4	Surface moisture resistance	—	$\geq$ Level 3	1# Level 4	Qualified
				2# Level 4	
				3# Level 4	
5	Breaking strength	N	$\geq 45$	82	Qualified
				49	
6	Breaking elongation	—	$\geq 15\%$	65%	Qualified
				74%	
7	Filter efficiency	—	$\geq 70\%$	99.8%	Qualified
				99.7%	
				99.8%	
				99.8%	
8	Antistatic	$\mu C/PC$	$\leq 0.6$	0.54	Qualified
				0.54	
9	flame retardancy	mm	$\leq 200$	The longitudinal 179	Qualified
				The transverse 194	
		s	$\leq 15$	The longitudinal 0.9	
				The transverse 0.6	
		s	$\leq 10$	The longitudinal 0.5	
				The transverse 0.4	
10	Microorganism	—	It should be sterile.	It is sterile.	Qualified
11	Oxirane residue	$\mu g/g$	$\leq 10$	0	Qualified

# 检验检测结果

## Test Result

[2020] WSZ FHL 第 0132 号

共 3 页 第 3 页

序号 Number	检验检测项目 Test item	单位 Unit	技术要求 Technical requirement	检验检测结果 Test result	单项 评价 Single Item decision																																																																			
10	静电衰减性能	s	≤0.5	0.3 0.4 0.3 0.4 0.3	合格																																																																			
11	抗静电性	μC/件	≤0.6	0.54	合格																																																																			
12	环氧乙烷残留量	μg/g	≤10	0	合格																																																																			
13	外观	—	防护服应干燥、清洁、无霉斑，表面不允许有粘连、裂缝、空洞等缺陷；针缝的针眼应作密封处理，针距每3cm应为8针~14针，线迹应为均匀、平直，无跳针。装有拉链的防护服拉链不能外露，拉头应能自锁。	防护服干燥、清洁、无霉斑，表面没有粘连、裂缝、空洞等缺陷；针缝的针眼有作密封处理，针距为12针/3cm，线迹均匀、平直，无跳针。装有拉链的防护服拉链没有外露，拉头能自锁。	合格																																																																			
14	结构	—	防护服应由连帽上衣、裤子组成，可分为连身式结构和分身式结构；防护服的结构应合理，穿脱方便，结合部位严密；袖口、脚踝口应采用弹性收口，帽子面部收口及腰部应采用弹性收口、拉伸收口或搭扣。	防护服为连身式结构；防护服的结构合理，穿脱方便，结合部位严密；袖口、脚踝口采用弹性收口，帽子面部收口及腰部采用弹性收口、拉伸收口及搭扣。	合格																																																																			
15	号型规格 (连身式)	cm	<table border="1"> <thead> <tr> <th>号型</th> <th>身长</th> <th>胸围</th> <th>袖长</th> <th>袖口</th> <th>脚口</th> </tr> </thead> <tbody> <tr> <td>160</td> <td>165</td> <td>120</td> <td>84</td> <td>18</td> <td>24</td> </tr> <tr> <td>165</td> <td>169</td> <td>125</td> <td>86</td> <td>18</td> <td>24</td> </tr> <tr> <td>170</td> <td>173</td> <td>130</td> <td>90</td> <td>18</td> <td>24</td> </tr> <tr> <td>175</td> <td>178</td> <td>135</td> <td>93</td> <td>18</td> <td>24</td> </tr> <tr> <td>180</td> <td>181</td> <td>140</td> <td>96</td> <td>18</td> <td>24</td> </tr> <tr> <td>185</td> <td>188</td> <td>145</td> <td>99</td> <td>18</td> <td>24</td> </tr> <tr> <td>偏差</td> <td>±2</td> <td>±2</td> <td>±2</td> <td>±2</td> <td>±2</td> </tr> </tbody> </table>	号型	身长	胸围	袖长	袖口	脚口	160	165	120	84	18	24	165	169	125	86	18	24	170	173	130	90	18	24	175	178	135	93	18	24	180	181	140	96	18	24	185	188	145	99	18	24	偏差	±2	±2	±2	±2	±2	<table border="1"> <thead> <tr> <th colspan="2">号型：185</th> </tr> <tr> <th>平均值</th> <th>偏差</th> </tr> </thead> <tbody> <tr> <td>身长</td> <td>188.4</td> <td>0.4</td> </tr> <tr> <td>胸围</td> <td>145.3</td> <td>0.3</td> </tr> <tr> <td>袖长</td> <td>99.3</td> <td>0.3</td> </tr> <tr> <td>袖口</td> <td>18.2</td> <td>0.2</td> </tr> <tr> <td>脚口</td> <td>24.3</td> <td>0.3</td> </tr> </tbody> </table>	号型：185		平均值	偏差	身长	188.4	0.4	胸围	145.3	0.3	袖长	99.3	0.3	袖口	18.2	0.2	脚口	24.3	0.3	合格
号型	身长	胸围	袖长	袖口	脚口																																																																			
160	165	120	84	18	24																																																																			
165	169	125	86	18	24																																																																			
170	173	130	90	18	24																																																																			
175	178	135	93	18	24																																																																			
180	181	140	96	18	24																																																																			
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偏差	±2	±2	±2	±2	±2																																																																			
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脚口	24.3	0.3																																																																						
符合																																																																								

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# Test Result

[2020] WSZ FHL NO.0132

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Number	Test item	Unit	Technical requirements	Test Result	Single Item decision																																																																					
12	Electrostatic attenuation	s	≤0.5	0.3 0.4 0.3 0.4 0.3	Qualified																																																																					
13	Appearance	—	Protective clothing should be dry, clean, mildew free, the surface is not allowed to adhesion, cracks, holes and other defects. The joint parts of protective clothing can be stitched, bonded or heat-bonded. The holes of the stitch shall be sealed, and the stitch spacing shall be 8-14 stitches per 3cm. After processing, such as bonding or heat bonding, to be flat, sealed, no bubbles. Zipper fitted protective clothing zipper can not leak, pull head should be able to self-lock.	The stitch spacing is 12 stitches per 3cm. Meet the requirements	Qualified																																																																					
14	Structure	—	Protective clothing should be made up of hooded jacket and trousers, which can be divided into double-body structure and double-body structure. The structure of protective clothing is reasonable, easy to wear and take off, and the joint parts are strict. Cuff, ankle mouth adopts elastic closure, cap face closure and waist closure adopts elastic closure, drawstring closure or buckle	Meet the requirements	Qualified																																																																					
15	Model Specification (One-piece pose)	cm	<table border="1"> <thead> <tr> <th>Model</th> <th>Body length</th> <th>Bust circumference</th> <th>Sleeve length</th> <th>Cuff</th> <th>INSTEP</th> </tr> </thead> <tbody> <tr> <td>160</td> <td>165</td> <td>120</td> <td>84</td> <td>18</td> <td>24</td> </tr> <tr> <td>165</td> <td>169</td> <td>125</td> <td>86</td> <td>18</td> <td>24</td> </tr> <tr> <td>170</td> <td>173</td> <td>130</td> <td>90</td> <td>18</td> <td>24</td> </tr> <tr> <td>175</td> <td>178</td> <td>135</td> <td>93</td> <td>18</td> <td>24</td> </tr> <tr> <td>180</td> <td>181</td> <td>140</td> <td>96</td> <td>18</td> <td>24</td> </tr> <tr> <td>185</td> <td>188</td> <td>145</td> <td>99</td> <td>18</td> <td>24</td> </tr> <tr> <td>Deviation</td> <td>±2</td> <td>±2</td> <td>±2</td> <td>±2</td> <td>±2</td> </tr> </tbody> </table>	Model	Body length	Bust circumference	Sleeve length	Cuff	INSTEP	160	165	120	84	18	24	165	169	125	86	18	24	170	173	130	90	18	24	175	178	135	93	18	24	180	181	140	96	18	24	185	188	145	99	18	24	Deviation	±2	±2	±2	±2	±2	<table border="1"> <thead> <tr> <th colspan="3">Model: 185</th> </tr> <tr> <th></th> <th>average</th> <th>Deviation</th> </tr> </thead> <tbody> <tr> <td>Body length</td> <td>188.4</td> <td>0.4</td> </tr> <tr> <td>Bust circumference</td> <td>145.3</td> <td>0.3</td> </tr> <tr> <td>Sleeve length</td> <td>99.3</td> <td>0.3</td> </tr> <tr> <td>Cuff</td> <td>18.2</td> <td>0.2</td> </tr> <tr> <td>INSTEP</td> <td>24.3</td> <td>0.3</td> </tr> </tbody> </table>	Model: 185				average	Deviation	Body length	188.4	0.4	Bust circumference	145.3	0.3	Sleeve length	99.3	0.3	Cuff	18.2	0.2	INSTEP	24.3	0.3	Qualified
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The End



DISPOSABLE EMERGENCY MEDICAL GARMENT-  
TEST REPORT (NON-STERILE)  
医用一次性防护服——检测报告(非无菌型)



# 检验检测报告

## Test Report

(2020) WSZ FHL 第0084号

湖南永霏特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO., LTD

产品名称 医用一次性防护服  
Product Name  
委托单位 湖南永霏特种防护用品有限公司  
Applicant  
生产单位 湖南永霏特种防护用品有限公司  
Manufacturer  
检验检测类别 委托检验  
Test Type

江苏国健检测技术有限公司  
Jiangsu Guojian Testing Technology Co.,Ltd



# Test Report

(2020) WSZ FHL NO.0084

湖南永霏特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO., LTD

Product Name Disposable Emergency Medical Garment  
Applicant Hunan Yourfield special protective equipment limited-liability company  
Manufacturer Hunan Yourfield special protective equipment limited-liability company  
Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co.,Ltd




# 检验检测报告

## Test Report

[2020] WSZ FHL 第 0084 号

共 3 页 第 1 页

产品名称 Product name	医用一次性防护服	规格型号 Specification	—
		商 标 Brand	—
委托单位/地址/联系电话 Applicant/Add/Tel	湖南永霏特种防护用品有限公司/湖南省湘潭市高新区双拥路 9 号创新创业园 A2 栋 401 号 /15200384607		
生产单位/地址/联系电话 Manufacturer/Add/Tel	湖南永霏特种防护用品有限公司/湖南省湘潭市高新区双拥路 9 号创新创业园 A2 栋 401 号 /15200384607		
样品等级 Sample grade	—	样品编号 Sample number	GW 0084-2020
样品数量 Sample quantity	3 件	样品接收日期 Receiving date of sample	2020 年 01 月 26 日
检验检测类别 Test type	委托检验	货号/批号/款号 Article number/Batch number/Style number	—
检验检测日期 Test date	2020/01/27~2020/02/07	检验检测地点 Test site	本公司检验室
样品状态 Sample state	符合检验检测要求		
检验检测依据 Test standard(s)	GB 19082-2009 《医用一次性防护服技术要求》		
检验检测项目 Test items	抗渗水性、透湿量、抗合成血液穿透性、表面抗湿性、断裂强力、断裂伸长率、过滤效率、阻燃性能、静电衰减性能、抗静电性、微生物指标、外观、结构、号型规格		
检验检测结论 Test conclusion	<p>样品经检验，所检项目符合 GB 19082-2009 标准规定的要求，具体检验结果详见第 2-3 页。</p> <p>签发日期 2020 年 3 月 17 日</p>		
备 注 Note	<p>样品信息由委托方提供，本报告仅对来样负责，报告有效期为 1 年。</p> 		

批准:



审核:

张慧芬


主检:

李琳

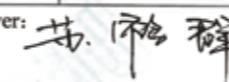
# Test Report

[2020] WSZ FHL NO.0084

Page 1 of 3

Product name	Disposable Emergency Medical Garment	Specification	—
		Brand	—
Applicant/Add /Tel	Hunan Yourfield special protective equipment limited-liability company /Building A2, No.9, Innovation Park, Shuangyong Road, High-Tech District, Xiangtan City, Hunan Province, P.R. China/15200384607		
Manufacturer/ Add/Tel	Hunan Yourfield special protective equipment limited-liability company /Building A2, No.9, Innovation Park, Shuangyong Road, High-Tech District, Xiangtan City, Hunan Province, P.R. China/15200384607		
Sample grade	—	Sample number	GW0084-2020
Sample quantity	3	Receiving date of sample	2020.01.26
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	2020/01/27~2020/02/07	Test site	Testing room
Sample state	Meet the requirements		
Test standard(s)	GB 19082-2009 《Technical requirements for disposable protective clothing for medical use》		
Test items	Water permeability、Moisture permeability、Synthetic blood penetration resistance、Surface moisture resistance、Breaking strength、Breaking elongation、Filtering efficiency、Antistatic、flame retardancy、Microorganism、Electrostatic attenuation、Appearance、Structure、Model Specification (One-piece pose)		
Test conclusion	<p>The sample upon examination, the projects meet the requirements of the GB 19082-2009 standard , the specific test results see page 2-3.</p> <p>签发日期 2020.3.17</p>		
Note	<p>The sample information is provided by Applicant. This report is only responsible for samples received.</p> 		

Approver:



Reviewer:

张慧芬

Main surveyor:

李琳

一技  
☆  
专用

永霏

## 检验检测结果 Test Result

[2020] WSZ FHL 第 0084 号

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序号 Number	检验检测项目 Test item	单位 Unit	技术要求 Technical requirement	检验检测结果 Test result	单项 评价 Single Item decision				
1	抗渗水性	kPa	≥1.67	23.3	合格				
2	透湿量	g/(m <sup>2</sup> ·d)	≥2500	5.90×10 <sup>3</sup>	合格				
3	抗合成血液穿透性	—	≥2级	6级	合格				
4	表面抗湿性	—	≥3级	4级	合格				
5	断裂强力	N	≥45	纵向	93	合格			
				横向	60				
6	断裂伸长率	—	≥15%	纵向	89%	合格			
				横向	90%				
7	过滤效率	—	≥70%	材料	99.8%	合格			
					99.6%				
					99.7%				
					99.6%				
				接缝	99.1%				
			≥70%		99.8%				
8	阻燃性能	mm	≤200	横向	167	合格			
				纵向	158				
				续燃时间	s		≤15	横向	13.8
								纵向	13.1
				阴燃时间	s		≤10	横向	0.5
								纵向	0.5
9	微生物指标	CFU/g	≤200	细菌菌落总数	<20	合格			
				大肠菌群	—		不得检出	未检出	
				绿脓杆菌	—		不得检出	未检出	
				金黄色葡萄球菌	—		不得检出	未检出	
				溶血性链球菌	—		不得检出	未检出	
				真菌菌落总数	CFU/g		≤100	<20	
10	静电衰减性能	s	≤0.5	0.4	合格				

## Test Result

[2020] WSZ FHL NO.0084

Page 2 of 3

Number	Test item	Unit	Technical requirements	Test Result	Single Item decision			
1	Water permeability	kPa	≥1.67	23.3	Qualified			
2	Moisture permeability	g/(m <sup>2</sup> ·d)	≥2500	5.90×10 <sup>3</sup>	Qualified			
3	Synthetic blood penetration resistance	—	≥Level 2	Level 6	Qualified			
4	Surface moisture resistance	—	≥Level 3	Level 4	Qualified			
5	Breaking strength	N	≥45	The longitudinal	93	Qualified		
				The transverse	60			
6	Breaking elongation	—	≥15%	The longitudinal	89%	Qualified		
				The transverse	90%			
7	Filter efficiency	—	≥70%	Key position material	99.8%	Qualified		
					99.6%			
					99.7%			
					99.6%			
				Seam	99.1%			
			≥70%		99.8%			
8	Antistatic	μC/PC	≤0.6	0.54	Qualified			
9	flame retardancy	mm	≤200	The longitudinal	167	Qualified		
				The transverse	158			
		s	≤15	The longitudinal	13.8			
				The transverse	13.1			
		s	≤10	The longitudinal	0.5			
				The transverse	0.5			
10	Microorganism	cfu/g	≤200	Bacterial colony count	<20	Qualified		
				Escherichia coli	—		Negative	Not detected
				Pseudomonas aeruginosa	—		Negative	Not detected
				Staphylococcus aureus	—		Negative	Not detected
				Hemolytic streptococcus	—		Negative	Not detected
				Fungal colony count	cfu/g		≤100	<20

## 检验检测结果 Test Result

[2020] WSZ FHL 第 0084 号

共 3 页 第 3 页

序号 Number	检验检测项目 Test item	单位 Unit	技术要求 Technical requirement	检验检测结果 Test result	单 项 评 价 Single Item decision							
11	抗静电性	μC/件	≤0.6	0.54	合格							
12	外观	—	防护服应干燥、清洁、无霉斑，表面不允许有粘连、裂缝、空洞等缺陷；针距每 3cm 应为 8 针~14 针，线迹应为均匀、平直，无跳针。粘合或热合等加工处理后的部位，应平整、密封，无气泡；装有拉链的防护服拉链不能外露，拉头应能自锁。	防护服干燥、清洁、无霉斑，表面没有粘连，裂缝、空洞等缺陷；针距为 13 针/3cm，线迹均匀、平直，无跳针。粘合或热合等加工处理后的部位，平整、密封，无气泡；装有拉链的防护服拉链没有外露，拉头能自锁。	合格							
13	结构	—	防护服应由连帽上衣、裤子组成，可分为连身式结构和分体式结构；防护服的结构应合理，穿脱方便，结合部位严密；袖口、脚踝口应采用弹性收口，帽子面部收口及腰部应采用弹性收口、拉伸收口或搭扣。	防护服由连帽上衣、裤子组成，为连身式结构；防护服的结构合理，穿脱方便，结合部位严密；袖口、脚踝口采用弹性收口，帽子面部收口及腰部采用弹性收口、拉伸收口及搭扣。	合格							
14	号型规格 (连身式)	cm	号型	身长	胸围	袖长	袖口	脚口	合格			
			Model: 185							平均值	偏差	
			160	165	120	84	18	24		身长	190	2
			165	169	125	86	18	24		胸围	146	1
			170	173	130	90	18	24		袖长	100	1
			175	178	135	93	18	24		袖口	19	1
			180	181	140	96	18	24		脚口	24	0
185	188	145	99	18	24	偏差	±2	±2				
符合												

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## Test Result

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Number	Test item	Unit	Technical requirements	Test Result	Single Item decision							
11	Electrostatic attenuation	s	≤0.5	0.4	Qualified							
12	Appearance	—	Protective clothing should be dry, clean, mildew free, the surface is not allowed to adhesion, cracks, holes and other defects. The joint parts of protective clothing can be stitched, bonded or heat-bonded. The holes of the stitch shall be sealed, and the stitch spacing shall be 8-14 stitches per 3cm. After processing, such as bonding or heat bonding, to be flat, sealed, no bubbles. Zipper fitted protective clothing zipper can not leak, pull head should be able to self-lock.	The stitch spacing is 12 stitches per 3cm. Meet the requirements	Qualified							
13	Structure	—	Protective clothing should be made up of hooded jacket and trousers, which can be divided into double-body structure and double-body structure. The structure of protective clothing is reasonable, easy to wear and take off, and the joint parts are strict. Cuff, ankle mouth adopts elastic closure, cap face closure and waist closure adopts elastic closure, drawstring closure or buckle	Meet the requirements	Qualified							
14	Model Specification (One-piece pose)	cm	Model	Body length	Bust circumference	Sleeve length	Cuff	INSTEP	Qualified			
			Model: 185							average	Deviation	
			160	165	120	84	18	24		Body length	190	2
			165	169	125	86	18	24		Bust circumference	146	1
			170	173	130	90	18	24		Sleeve length	100	1
			175	178	135	93	18	24		Cuff	19	1
			180	181	140	96	18	24		INSTEP	24	0
			185	188	145	99	18	24		Deviation	±2	±2
Note												

The End



检验检测报告



No: 200037473

防伪查询网址: www.gttc.net.cn  
防伪码: FIYG-0659-54

共5页 第1页



委托单位	湖南永霏特种防护用品有限公司 地址: 湖南省湘潭市高新区双拥路9号创新创业园A2栋		
客户认定信息	手术衣 5件 商标: 永霏 批号款号: YF-SH001 颜色: 蓝色 材质: 无纺布 号型规格: 均码 生产单位: 湖南永霏特种防护用品有限公司		
检验性质	委托检测	样品受理/测试开始日期	2020-03-13
		报告签发日期	2020-03-25
判定依据	YY/T 0506.2-2016 《病人、医护人员和器械用手术单、手术衣和洁净服 第2部分: 性能要求和试验方法》 湖南永霏特种防护用品有限公司 HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO. LTD		
综合检验结论	仅供存档 严禁商用 违法必究		
检验检测结果	检验检测项目	判定依据	判定
	洁净度-微生物	YY/T 0506.2-2016	符合
	阻干态微生物穿透	---	---
	阻湿态微生物	YY/T 0506.2-2016	符合
	抗渗水性	YY/T 0506.2-2016	符合
	断裂强力[干态]	YY/T 0506.2-2016	符合
	断裂强力[湿态]	YY/T 0506.2-2016	符合
	干态落絮	YY/T 0506.2-2016	符合
	洁净度-微粒物质	YY/T 0506.2-2016	符合
	胀破强度[干态]	YY/T 0506.2-2016	符合
	胀破强度[湿态]	YY/T 0506.2-2016	符合
备注	本报告中检验检测项目均在相应标准规定的环境条件下进行(有注明的除外) 复印件、副本未重新加盖报告书确认章无效。 本报告检验检测地址为广州市番禺区珠江路1号。		



样品图片

No: 200037473  
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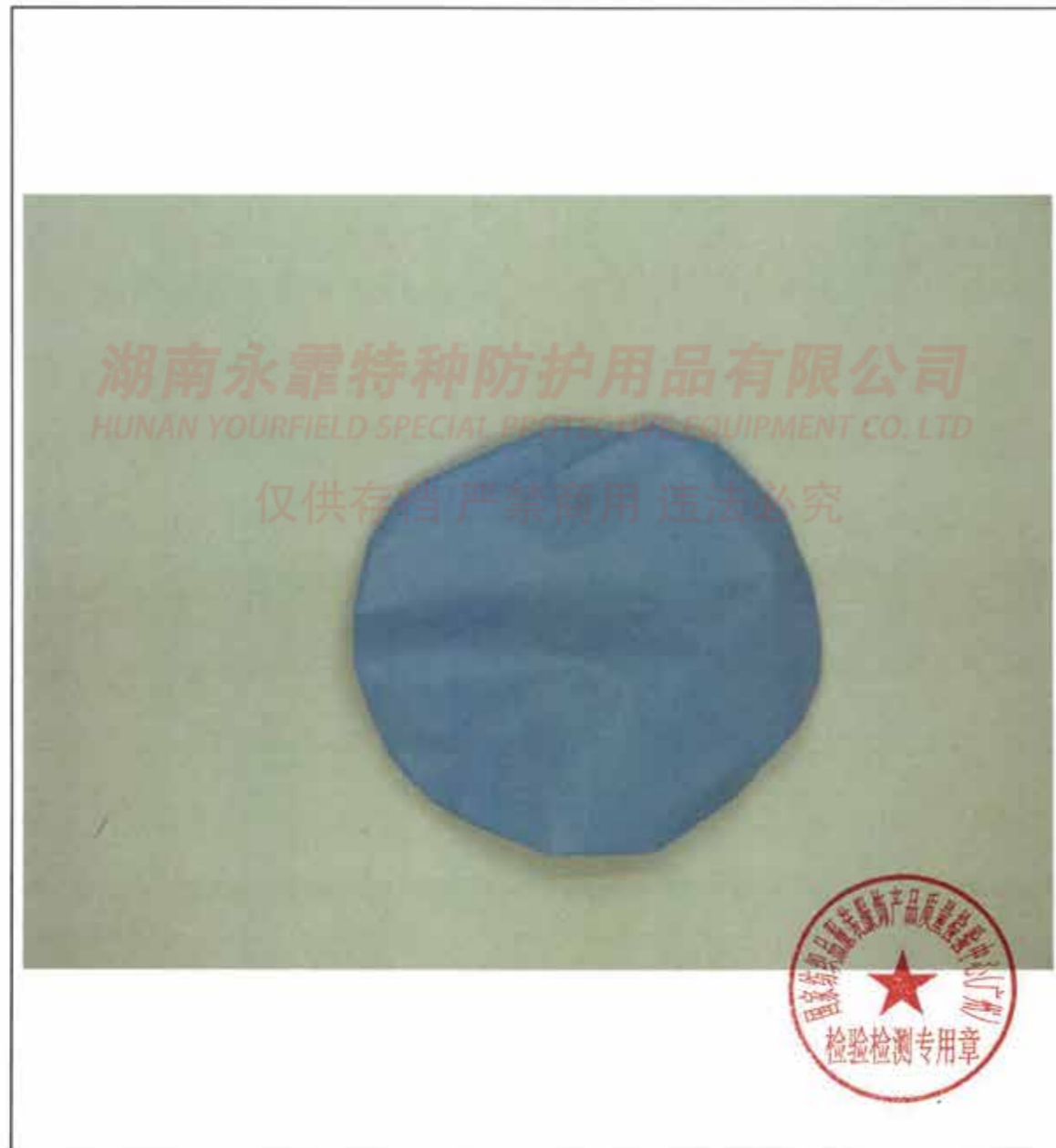
签发: 刘圆 工程师

刘圆



样品图片

No:200037473  
共5页 第3页



检验检测报告附页

No:200037473  
共5页 第4页

检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●洁净度-微生物	YY/T 0506.7-2014 洗脱参数: 运行频率:200r/min 运行时间:1min	洁净度-微生物: ≤300 CFU/dm <sup>2</sup> (手术衣标准性能关键区域)	洗脱菌落总数: 0 CFU 回收率: 80% 修正系数: 1.25 洁净度-微生物: 0 CFU/dm <sup>2</sup>	符合	
●阻干态微生物穿透(CFU)	YY/T 0506.5-2009 枯草芽孢杆菌ATCC 9372第4代 芽孢滑石粉中枯草杆菌芽孢浓度: 1.9×10 <sup>8</sup> CFU/g滑石粉 试样件数: 12 振动频率: 20800次/min 振动时间: 30min	---	8	---	
●阻湿态微生物	YY/T 0506.6-2009 温度:24.5℃ 相对湿度:50.5% 琼脂离平皿口距离:3mm 载菌材料:30μm厚的溶剂铸制聚氨酯膜	屏障指数 ≥2.8 (手术衣标准性能关键区域)	屏障指数 4.3	符合	
●抗渗水性 (cmH <sub>2</sub> O)	YY/T 0506.2-2016 附录A.5 压力速率: 10cmH <sub>2</sub> O/min 水温:20.0℃ 试样正面接触水	≥20 (手术衣标准性能关键区域)	54.0	符合	
●断裂强力(N) [干态]	GB/T 24218.3-2010 干态 夹距:200mm 速度:100mm/min	纵向 ≥20 横向 ≥20 (手术衣标准性能关键区域)	纵向 75.6 横向 47.3	符合	
●断裂强力(N) [湿态]	GB/T 24218.3-2010 湿态 夹距:200mm 速度:100mm/min	纵向 ≥20 横向 ≥20 (手术衣标准性能关键区域)	纵向 75.7 横向 46.7	符合	
●干态落絮	YY/T 0506.2-2016 附录A.4 计数微粒尺寸范围: 3 μm~25 μm	落絮系数: ≤4.0 (手术衣标准性能关键区域)	落絮系数: A面 3.1 B面 3.1 平均值 3.1	符合	



## 检验检测报告附页

No: 200037473

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检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
● 洁净度-微粒物质	YY/T 0506.2-2016 附录A.3 计数微粒尺寸范围: 3 μm~25 μm	IPM: ≤3.5 (手术衣标准性能关键区域)	IPM: A面 2.9 B面 2.8 平均值 2.9	符合	
● 胀破强度 (kPa) [干态]	YY/T 0506.2-2016 附录A.6 干态 试验面积: 50cm <sup>2</sup>	≥40 (手术衣标准性能关键区域)	78.1	符合	
● 胀破强度 (kPa) [湿态]	YY/T 0506.2-2016 附录A.6 湿态 试验面积: 50cm <sup>2</sup>	≥40 (手术衣标准性能关键区域)	85.4	符合	

湖南永霏特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO., LTD

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备注  
(本栏空白)



—— 本报告结束 ——



## Certificate

No. ICR Polska/M8809920



**Name and address of certificate owner:** Hunan Yourfield Special Protective Equipment co., Ltd  
Torch Innovation Park, High-Tech District, Xiangtan, Hunan

**Name and address of manufacturer:** Hunan Yourfield Special Protective Equipment co., Ltd  
Torch Innovation Park, High-Tech District, Xiangtan, Hunan

**Product name:** Disposable surgical gown

**Product types:** YF-YY20015

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 14126:2003+AC:2004

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by EUROPE CERTIFICATION UNION CO., LTD laboratory.

**No. of test reports:** ESC-HNYF-2020-3

**Certificate issue date:** 26.03.2020

**Expiration date:** 25.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8899.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Director: Rafał Kalinowski

Warsaw, 26.03.2020

ICR Polska Co. Ltd.  
ul. Plac Przymierza 6, 03-944 Warszawa  
www.icrpolska.com, e-mail: icrpolska@icrqa.com



Type5

Type6

International Certification Registrar International Certification Registrar



# Certificate

No. ICR Polska/M8810020



**Name and address of certificate owner:** Hunan Yourfield Special Protective Equipment co., Ltd  
Torch Tnnovation Park, High-Tech District, Xiangtan, Hunan

**Name and address of manufacturer:** Hunan Yourfield Special Protective Equipment co., Ltd  
Torch Tnnovation Park, High-Tech District, Xiangtan, Hunan

**Product name:** protection suit with a hood--white color

**Product types:** YF-GY20001

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 14126:2003+AC:2004

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by EUROPE CERTIFICATION UNION CO., LTD laboratory.

**No. of test reports:** ESC-HNYF-2020-3

**Certificate issue date:** 26.03.2020

**Expiration date:** 25.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-88100.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Director: Rafał Kalinowski

Warsaw, 26.03.2020

ICR Polska Co. Ltd.  
ul. Plac Przymierza 6, 03-944 Warszawa  
www.icrpolska.com, e-mail: icrpolska@icrq.com



# Certificate

No. ICR Polska/M8810120



**Name and address of certificate owner:** Hunan Yourfield Special Protective Equipment co., Ltd  
Torch Tnnovation Park, High-Tech District, Xiangtan, Hunan

**Name and address of manufacturer:** Hunan Yourfield Special Protective Equipment co., Ltd  
Torch Tnnovation Park, High-Tech District, Xiangtan, Hunan

**Product name:** protection suit with a hood--white color

**Product types:** YF-GY20002

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 14126:2003+AC:2004

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by EUROPE CERTIFICATION UNION CO., LTD laboratory.

**No. of test reports:** ESC-HNYF-2020-3

**Certificate issue date:** 26.03.2020

**Expiration date:** 25.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/1020-8802.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Director: Rafał Kalinowski

Warsaw, 26.03.2020

ICR Polska Co. Ltd.  
ul. Plac Przymierza 6, 03-944 Warszawa  
www.icrpolska.com, e-mail: icrpolska@icrq.com





Form QAT\_10-M04, version 00, effective since March 6th, 2020

## CE Documentation Review



No. 4Q200320.HYSUW81

**Holder:** Hunan Yourfield Special Protective Equipment Co., Ltd.  
Building A2, No.9, Innovation Park, Shuangyong Road, High-Tech District, Xiangtan City, Hunan Province, P.R.China.

**Review goal:** Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

**Product:** Disposable Emergency Medical Garment (Not Sterile)

**Model(s):** YF-YY20013 Coverall, YF-YY20014 Coverall

**Classification:** Class I (Not Sterile)  
(accordingly to the Manufacturer's declaration)

**Review output:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. 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)

Date of issue 20 March 2020

Approver  
ECM Service Director  
Luca Bedonni

Expiry date 19 March 2025

Technical Expert  
Amanda Pavia

Ente Certificazione Macchine

Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy  
☎ +39.0516705141 ☎ +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Form QAT\_10-M04, version 00, effective since March 6th, 2020

## CE Documentation Review



No. 4Q200320.HYSUW80

**Holder:** Hunan Yourfield Special Protective Equipment Co., Ltd.  
Building A2, No.9, Innovation Park, Shuangyong Road, High-Tech District, Xiangtan City, Hunan Province, P.R.China.

**Review goal:** Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

**Product:** Daily Protective Mask (Not Sterile)

**Model(s):** YF-YY20017, YF-YY20018

**Classification:** Class I (Not Sterile)  
(accordingly to the Manufacturer's declaration)

**Review output:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. 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)

Date of issue 20 March 2020

Approver  
ECM Service Director  
Luca Bedonni

Expiry date 19 March 2025

Technical Expert  
Amanda Pavia

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Fiscal Year 2020

### CERTIFICATION OF FDA REGISTRATION

This certifies that:

**Hunan Yourfield Special Protective Equipment co., Ltd**  
**Building A2, No.9, Innovation Park, Shuangyong Road,**  
**High-Tech District, Xiangtan City, Hunan Province, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Changsha Nande Testing Technology Co., Ltd.

湖南永霏特种防护用品有限公司  
 HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO., LTD

Owner/Operator Number: 10063622

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D376810	KHA	MASK, SCAVENGING	Daily protective mask
D376811	OEA	Non-surgical isolation gown	disposable Emergency Medical Garment

CNT 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. CNT 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. CNT 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, CNT is not affiliated with the U.S. Food and Drug Administration.

Chief engineer  
 Issued: 03/20/2020  
 Expiration Date: 12/31/2020

Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: [webmail@oc.fda.gov](mailto:webmail@oc.fda.gov)

NO. (序号)	Product Name (产品名称)	Specifications (规格型号)	Quantity (PCS/CTNS)	N.W. (KG)净重	G.W. (KG)毛重	Measurements (外箱尺寸)			CTNS (箱)	CBM Total (体积)
						L(m)长	W(m)宽	H(m)高		
1	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	170CM, without shoe covers	30	8.1	9.1	0.56	0.4	0.5	1	0.112
2	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	175CM, without shoe covers	30	8.5	9.5	0.56	0.4	0.5	1	0.112
3	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	180CM, without shoe covers	30	8.8	9.8	0.56	0.4	0.5	1	0.112
4	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	190CM, without shoe covers	30	9.6	10.6	0.56	0.4	0.5	1	0.112
5	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	170CM, with shoe covers	30	9.5	10.5	0.56	0.4	0.5	1	0.112
6	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	175CM, with shoe covers	30	9.9	10.9	0.56	0.4	0.5	1	0.112
7	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	180CM, with shoe covers	30	9.6	10.6	0.56	0.4	0.5	1	0.112
8	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	170CM, without shoe covers	30	8.7	9.7	0.56	0.4	0.5	1	0.112
9	Disposable Emergency Medical Protective Coverall (sterile/non-sterile)	180CM, without shoe covers	30	9.6	10.6	0.56	0.4	0.5	1	0.112

序号	产品名称	规格型号	数量 (件/箱)	净重 (KG)	毛重 (KG)	外箱尺寸			箱数	体积 (m³)
						长(m)	宽(m)	高(m)		
1	医用一次性防护服(无菌型/非无菌型)	170CM, 无脚套	30	8.1	9.1	0.55	0.39	0.5	1	0.10725
2	医用一次性防护服(无菌型/非无菌型)	175CM, 无脚套	30	8.5	9.5	0.55	0.39	0.5	1	0.10725
3	医用一次性防护服(无菌型/非无菌型)	180CM, 无脚套	30	8.8	9.8	0.55	0.39	0.5	1	0.10725
4	医用一次性防护服(无菌型/非无菌型)	190CM, 无脚套	30	9.6	10.6	0.55	0.39	0.5	1	0.10725
5	医用一次性防护服(无菌型/非无菌型)	170CM, 有脚套	30	9.5	10.5	0.55	0.39	0.5	1	0.10725
6	医用一次性防护服(无菌型/非无菌型)	175CM, 有脚套	30	9.9	10.9	0.55	0.39	0.5	1	0.10725
7	医用一次性防护服(无菌型/非无菌型)	180CM, 有脚套	30	9.6	10.6	0.55	0.39	0.5	1	0.10725
8	医用一次性防护服(无菌型/非无菌型)	170CM, 无脚套	30	8.7	9.7	0.55	0.39	0.5	1	0.10725
9	医用一次性防护服(无菌型/非无菌型)	180CM, 无脚套	30	9.6	10.6	0.55	0.39	0.5	1	0.10725

PRODUCT INTRODUCTION -  
DISPOSABLE EMERGENCY MEDICAL GARMENT(STERILE)

## 产品介绍 —— 医用一次性防护服(无菌型)



**产品名称:**医用一次性防护服

**产品型号:** I 型防护服(由连帽上衣、裤子组成)

**产品结构:**连身式(无菌型)

**执行标准:**GB19082-2009

**灭菌方式:**环氧乙烷或辐照

**适用范围:**供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用.

**有效期:**两年(环氧乙烷)  
一个月(辐照)

**Product name:** Disposable Emergency Medical Garment

**Product type:** type I protective suit (consisting of hooded top and trousers)

**Product structure:** coverall (sterile)

**Implementation standard:** GB19082-2009

**Sterilization method:** ethylene oxide or irradiation

**Scope of application:** It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work.

**Validity period:** two years (ethylene oxide)  
one month (irradiation)

PRODUCT INTRODUCTION -  
DISPOSABLE EMERGENCY MEDICAL GARMENT (STERILE)  
产品介绍 —— 医用一次性防护服(无菌型)



**产品名称:**医用一次性防护服

**产品型号:** II 型防护服(由连帽上衣、裤子、鞋套组成)

**产品结构:**连身式(无菌型)

**执行标准:**GB19082-2009

**灭菌方式:**环氧乙烷或辐照

**适用范围:**供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用.

**有效期:**两年(环氧乙烷)  
一个月(辐照)

**Product name:** Disposable Emergency Medical Garment

**Product type:** type II protective suit (consisting of hooded top, trousers and shoe covers)

**Product structure:** coverall (sterile)

**Implementation standard:** GB19082-2009

**Sterilization method:** ethylene oxide or irradiation

**Scope of application:** It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work.

**Validity period:** two years (ethylene oxide)  
one month (irradiation)

产品介绍 —— 医用一次性防护服(非无菌型)



**产品名称:**医用一次性防护服

**产品型号:**I 型防护服(由连帽上衣、裤子组成)

**产品结构:**连身式(非无菌型)

**执行标准:**GB19082-2009

**灭菌方式:**环氧乙烷或辐照

**适用范围:**供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用.不能用于隔离重症监护病区(房)等有严格微生物指标控制的场所.

**有效期:**两年(环氧乙烷)

一个月(辐照)

**Product name:** Disposable Emergency Medical Garment

**Product type:** type I protective suit (consisting of hooded top and trousers)

**Product structure:** coverall (non-sterile)

**Implementation standard:** GB19082-2009

**Sterilization method:** ethylene oxide or irradiation

**Scope of application:** It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work, but it cannot be used in such places as isolating intensive care units (rooms) with the requirement for strict microbiological indicator control.

**Validity period:** two years (ethylene oxide)

one month (irradiation)

产品介绍 —— 医用一次性防护服(非无菌型)



**产品名称:**医用一次性防护服

**产品型号:** II 型防护服(由连帽上衣、裤子、鞋套组成)

**产品结构:**连身式(非无菌型)

**执行标准:**GB19082-2009

**灭菌方式:**环氧乙烷或辐照

**适用范围:**供临床医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用.不能用于隔离重症监护病区(房)等有严格微生物指标控制的场所.

**有效期:**两年(环氧乙烷)

一个月(辐照)

**Product name:** Disposable Emergency Medical Garment

**Product type:** type II protective suit (consisting of hooded top, trousers and shoe covers)

**Product structure:** coverall (non-sterile)

**Implementation standard:** GB19082-2009

**Sterilization method:** ethylene oxide or irradiation

**Scope of application:** It is used to provide barrier and protection for clinical medical personnel when they contact with the blood, body fluids and secretions of patients with potential infection risk and particulates in the air at work, but it cannot be used in such places as isolating intensive care units (rooms) with the requirement for strict microbiological indicator control.

**Validity period:** two years (ethylene oxide)

one month (irradiation)

PRODUCT INTRODUCTION - Disposable Emergency Medical Garment

产品介绍——医用一次性防护服

SIZE SPECIFICATION

尺码表



号型	身長(厘米)	胸围(厘米)	袖长(厘米)	脚口(厘米)
160-I	165	120	84	23
165-I	169	125	86	23
170-I	173	130	88	24
175-I	178	135	90	24
180-I	183	140	93	25
185-I	188	145	96	25
190-I	193	150	99	26
195-I	198	155	102	26
200-I	203	160	105	27
偏差	±2	±2	±2	±2

号型	身長(厘米)	胸围(厘米)	袖长(厘米)	脚口(厘米)	鞋盖高(厘米)	鞋盖长(厘米)
160-II	165	120	84	38	19	37
165-II	169	125	86	38	19	37
170-II	173	130	88	40	19	38
175-II	178	135	90	40	19	38
180-II	183	140	93	42	19	39
185-II	188	145	96	42	19	39
190-II	193	150	99	44	19	40
195-II	198	155	102	44	19	40
200-II	203	160	105	46	19	41
偏差	±2	±2	±2	±2	±1	±1

TYPE	LENGTH(IN)	BUST(IN)	SLEEVE(IN)	ANKLE(IN)
M-I	68	47	34	9.45
L-I	70	49	35	9.45
XL-I	72	51	37	9.45
XXL-I	74	53	38	9.45
XXXL-I	76	55	39	9.45
XXXXL-I	78	57	40	9.45
XXXXXL-I	80	59	41	9.45
XXXXXXL-I	82	61	43	9.45
Deviation	±2	±2	±2	±2

TYPE	LENGTH(IN)	BUST(IN)	SLEEVE(IN)	ANKLE(IN)	SHOE COVER HEIGHT(IN)	SHOE COVER LENGTH(IN)
M-II	68	47	34	15	7.48	14.5
L-II	70	49	35	16	7.48	14.9
XL-II	72	51	37	16	7.48	14.9
XXL-II	74	53	38	17	7.48	15.3
XXXL-II	76	55	39	17	7.48	15.3
XXXXL-II	78	57	40	18	7.48	15.7
XXXXXL-II	80	59	41	18	7.48	15.7
XXXXXXL-II	82	61	43	19	7.48	16.1
Deviation	±2	±2	±2	±2	±2	±2



湖南永霏特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO. LTD

仅供存档 严禁商用 违法必究

**产品名称:**隔离服

**产品型号:**连身式(由连帽上衣、裤子组成)

**产品规格:**S-5XL

**产品特点:**

- 1.弹性头罩、腰间、脚踝设计,便于安全穿着和自由行动
- 2.加强型插裆设计,增强耐用性
- 3.新型材料,柔软、轻薄、透气、舒适
- 4.可与其它个体防护用品配合使用,有效提高安全性

**有效期:**五年

**Product name:** isolation gown

**Product type:** coverall structure (consisting of hooded top and trousers)

**Product specification:** S-5XL

**Product features:**

1. Elastic hood, with waist and ankle design, in favor of safe wearing and free movement
2. Reinforced crotch design, to enhance durability
3. New materials, soft, light, breathable and comfortable
4. It can be used together with other personal protective equipment to effectively improve safety.

**Validity period:** five years





**产品名称:**一次性使用手术衣

**产品规格:**S-6XL

**产品结构:**由衣身和衣袖组成,由无菌供应

**产品性能:**应平整、清洁无污渍、无破损、热合牢固,不应有破洞现象

**适用范围:**适用于已知病人血液中无传染性病毒的手术时医护人员及病人防护用。

**执行标准:**YY/T 0506.2-2016

**灭菌方式:**环氧乙烷

**有效期:**两年

**Product name:** Disposable surgical gown

**Product specification:** S-6XL

**Product structure:** consisting of gown body and sleeves, supplied in a sterile manner.

**Product performance:**smooth, clean, free of stains, no damage, firm in heat sealing, and no holes.

**Scope of application:** It is used by medical personnel and patient for protection during operation where no infectious virus exists in the blood of the patient.

**Implementation standard:** YY/T 0506.2-2016

**Sterilization method:** ethylene oxide

**Validity period:** two years

产品介绍 — CRPI日常防护口罩



**产品名称:**可重复使用口罩(平面款)

**产品规格:**均码--17cm\*9cm

儿童款--15cm\*8.5cm

**产品结构:**口罩体+鼻夹+耳带

**产品材质:**外层和里层棉麻质地,舒适透气,天然抑菌耐水洗,中间层凝胶膜由两层无纺布包裹,高效过滤细菌及颗粒物.

**产品性能:**细菌过滤效率 $\geq 97\%$ (反复消毒三次,过滤效率无明显变化.)

**产品用途:**适用于防护空气中的颗粒物

**产品包装:**独立包装

**使用次数:**20次

**执行标准:**GB32610-2016

**灭菌方式:**高温灭菌

**有效期:**两年

**Product name:** CRPI Daily Protective Mask (flat type)

**Product specification:** average size - 17cm\*9cm

For children -- 15cm\*8.5cm

**Product structure:** mask body + nose clip + ear loop

**Product material:** Both the outer and inner layers are cotton and linen, comfortable and breathable, natural antibacterial and washable. The middle layer is gel film wrapped by two layers of non-woven fabrics, and can efficiently filter bacteria and non-oily particles.

**Product performance:** bacterial filtration efficiency  $\geq 99.9\%$  (no obvious change in filtration efficiency after being disinfected for three times)

**Application:** to prevent particles in the air.

**Product packaging:** independent packaging (two pieces in one box)

**Number of uses:** 20 times

**Implementation standard:** GB2626-2019

**Sterilization method:** high temperature sterilization

**Validity period:** two years

产品介绍 —— 可重复适用口罩



湖南永霏特种防护用品有限公司  
HUNAN YOURFIELD SPECIAL PROTECTIVE EQUIPMENT CO., LTD

仅供存档 严禁商用 违法必究

**产品名称:**CRPI 日常防护口罩(立体款)

**产品规格:**均码--20cm\*14cm

儿童款--19cm\*13.5cm

**产品结构:**口罩体+鼻夹+耳带

**产品材质:**外层和里层棉麻质地, 舒适透气, 天然抑菌耐水洗, 中间层凝胶膜由两层无纺布包裹, 高效过滤细菌及颗粒物.

**产品性能:**细菌过滤效率 $\geq 97\%$  (反复消毒三次, 过滤效率无明显变化.)

**产品用途:**适用于防护空气中的颗粒物

**产品包装:**独立包装

**使用次数:**20次

**执行标准:**GB32610-2016

**灭菌方式:**高温灭菌

**有效期:**两年

**Product name:** CRPI Daily Protective Mask (stereo type)

**Product specification:** average size - 20cm\*14cm

For children -- 19cm\*13.5cm

**Product structure:** mask body + nose clip + ear loop

**Product material:** Both the outer and inner layers are cotton and linen, comfortable and breathable, natural antibacterial and washable. The middle layer is gel film wrapped by two layers of non-woven fabrics, and can efficiently filter bacteria and non-oily particles.

**Product performance:** bacterial filtration efficiency  $\geq 99.9\%$  (no obvious change in filtration efficiency after being disinfected for three times)

**Application:** to prevent particles in the air.

**Product packaging:** independent packaging (two pieces in one box)

**Number of uses:** 20 times

**Implementation standard:** GB2626-2019

**Sterilization method:** high temperature sterilization

**Validity period:** two years

COMPANY STYLE  
公司风采





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PLANT STYLE  
工厂风采

