Disposable Protective Clothing
ESCALIER®, Disposable Protective Clothing

**Product Name**
Disposable Protective Clothing, hereinafter referred to as “protective clothing”.

**Model**
One piece coverall

**Material**
- Outer layer 30g breathable laminate film
- Inner layer 30g PP nonwoven fabric plus 3g glue, fabric weight 63g

**Main Structural Components**
The product consists of a hooded top and trousers.

**Scope of Application**
Provides barrier and protection to clinical medical staff when they contact with blood, body fluid and secretion of potentially infectious patients during work.

**Product Performance**
GB 19082-2009
The key features include

- Knit cuffs with elasticized waist and ankles for increased wearer comfort and freedom of movement.
- Taped seams to help provide additional protection.
- Offers protection from certain biological contaminants (tested according to GB 19082-2009 & EN ISO 16388).

License & Certificates

Medical Device Registration Certificate No
浙械注准20202141041

Medical Device Production License No
浙食药监械生产许20200038号

FDA Owner/Operator Number 10062956

CE Declaration of Conformity 2017/745
Performance

This product was tested by Zhejiang Institute of Medical Device Supervision & Testing

Test method: GB 19082-2009

The test report number is Z20200473 & Z20200585. The table below shows the performance when tested under laboratory conditions.

<table>
<thead>
<tr>
<th>Test</th>
<th>Unit</th>
<th>Requirement</th>
<th>Results</th>
<th>Individual Judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid Penetration Resistance</td>
<td>kPa 17cmH₂O</td>
<td>≥ 1.67</td>
<td>15.46</td>
<td>Pass</td>
</tr>
<tr>
<td>Tensile Strength Longitude</td>
<td>N</td>
<td>≥ 45</td>
<td>128</td>
<td>Pass</td>
</tr>
<tr>
<td>Tensile Strength Traverse</td>
<td>N</td>
<td>≥ 45</td>
<td>53</td>
<td>Pass</td>
</tr>
<tr>
<td>Filtration Efficiency (%) 82L/min</td>
<td>---</td>
<td>≥ 70</td>
<td>97.98~100</td>
<td>Pass</td>
</tr>
<tr>
<td>Moisture Permeability</td>
<td>---</td>
<td>≥ 2500g/(m²d)</td>
<td>4440</td>
<td>Pass</td>
</tr>
</tbody>
</table>

The main performance index of the product is liquid barrier function. The elongation at break, filtration efficiency, etc. are all in accordance with the technical requirements and standards of GB 19082-2009. The conclusion shows the products meet the requirements of the standards of GB 19082-2009. Please note that the tests may not reflect the reality of use and do not account for factors such as excessive heat and mechanical wear.
The stitch adopts the rubber tape sealing technology to improve the ability of protection. The fabric with strong anti permeability, good air permeability, and moisture permeability; anti-static, durable, scratch resistant and ripstop; The product is light, soft and comfortable to wear with effectively resist the invasion of human body by droplets / blood / body fluid/ pollutants / viruses.
ESCALIER®
Disposable Protective Clothing

Materials & Others

- **Suit:** Outer layer 30g breathable Laminate Film
  Inner layer 30g PP nonwoven fabric (100% polypropylene) + 3g glue

- **Size:** 160(XS), 165(S), 170(M),
  175(L), 180(XL), 185(XXL)

- **Seams:** Polypropylene, Blue

- **Zipper:** Nylon on Polyester Braid

- **Color:** Solid white

- **Basis Weight:** 63 grams/m2

- **Sterilization:** Non Sterilized
  or with Ethylene Oxide Sterilized
  (according to customer request)

- **No known contraindications found.**
Typical Applications

Typical applications may include exposure to non-infectious blood and bodily fluids, secretion of potentially infectious patients, pharmaceutical, cleanroom applications, and general clean-up.

In all cases a risk assessment should be carried out. Users must be trained and have read all Operation Manual before using.

Use limitations and performance data should be considered to ascertain the protection required. If in doubt, contact a safety professional.

Precautions: The non-sterile version cannot be used in places with strict microbiological index control, such as ICU.
Use Limitations
Do not use for:

- Contact with sparks or flames, or combustible liquids, heavy oils.
- Exposure situations resulting in directional spray or liquid build-up on the suit.
- Environments with exposure to hazardous substances beyond GB 19082-2009.
- Environments with conditions of excessive heat
- Caution for those who are allergic to nonwovens.

Storage & Transportation

- Stored in original packaging in a clean room with a relative humidity of not more than 80% and well-ventilated environment with no corrosive gases.
- The transportation process should be performed in accordance with the contract's provisions. Avoid heavy pressure deformation, direct sunlight, hard objects scratching and rain or snow or liquid leaching.

Symbol

Do not reuse
Refer to the operating manual
Do not use if package is damaged
Precautions, Warnings & Tips

1. The product is for single use, it is forbidden to reuse.

2. Please check the protective clothing for damage before wearing; the sleeves should not touch the face and collar when wearing. Replace a new one immediately if leakage or damaged is found. Please take precaution to avoid contamination when taking off.

3. The protective clothing is limited to put on and take off in the prescribed area.

4. The protective clothing can be used continuously when medical workers contact multiple patients with similar infectious diseases. In contact with suspected patients, the protective clothing should be changed between each patient.

5. When protective clothing is contaminated by patient's blood, body fluids and dirt, it should be replaced in time.

6. The product must be disposed of as requirements of the <Medical Waste Management Regulations> after used.
Disposable Protective Clothing

Instructions

1. Take out protective clothing
   Tear open the outside packing and remove the protective clothing.

2. Wear protective clothing
   The order of wearing one-piece protective clothing is to wear pants first, then top and hood, finally zip up the zipper.

3. Remove protective clothing
   First pull-down zipper to the bottom of the protective clothing (see sketch 1). Lift the hood upwards off the head then take off sleeves (see sketches 2 & 3). Roll off the clothing from top to bottom (see sketch 4). Roll inward the contaminated side until the clothing is completely removed then put the clothing into the medical waste bag (see sketch 5).
# Size Spec

<table>
<thead>
<tr>
<th>Specifications</th>
<th>160 (XS)</th>
<th>165 (S)</th>
<th>170 (M)</th>
<th>175 (L)</th>
<th>180 (XL)</th>
<th>185 (XXL)</th>
<th>Tolerance (+/-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length from cap to toe</td>
<td>175</td>
<td>179</td>
<td>183</td>
<td>188</td>
<td>191</td>
<td>198</td>
<td>2</td>
</tr>
<tr>
<td>Bust</td>
<td>120</td>
<td>125</td>
<td>130</td>
<td>135</td>
<td>140</td>
<td>145</td>
<td>2</td>
</tr>
<tr>
<td>Sleeve length (To back center)</td>
<td>84</td>
<td>86</td>
<td>90</td>
<td>93</td>
<td>96</td>
<td>99</td>
<td>2</td>
</tr>
<tr>
<td>Relax measurement of leg opening*2</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>2</td>
</tr>
<tr>
<td>Relax measurement of Cuff *2</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>Waist rubber band</td>
<td>53.0</td>
<td>54.0</td>
<td>55.5</td>
<td>57.0</td>
<td>58.0</td>
<td>59.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Cap rubber band</td>
<td>29.0</td>
<td>30.0</td>
<td>30.0</td>
<td>30.0</td>
<td>31.0</td>
<td>31.0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Export Qualification</th>
<th>Country</th>
<th>Standard</th>
<th>Quality Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE</td>
<td>European Union</td>
<td>Medical class I</td>
<td>EN14126</td>
</tr>
<tr>
<td>FDA</td>
<td>America</td>
<td>Medical class I</td>
<td></td>
</tr>
</tbody>
</table>

02 April 2020
Barbara Hung +86 13777423388
barbara@stageleather.com
## Protective Clothing Sizing Chart

<table>
<thead>
<tr>
<th>inch/cm</th>
<th>lb/kg</th>
<th>90</th>
<th>100</th>
<th>110</th>
<th>120</th>
<th>130</th>
<th>140</th>
<th>150</th>
<th>160</th>
<th>170</th>
<th>180</th>
<th>190</th>
<th>200</th>
<th>210</th>
<th>220</th>
</tr>
</thead>
<tbody>
<tr>
<td>5’1”</td>
<td>155</td>
<td>XS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5’3”</td>
<td>160</td>
<td>160</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5’5”</td>
<td>165</td>
<td>165</td>
<td>M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5’7”</td>
<td>170</td>
<td>170</td>
<td>L</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5’9”</td>
<td>175</td>
<td>175</td>
<td>XL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5’11”</td>
<td>180</td>
<td>180</td>
<td>XXL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6’1”</td>
<td>185</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
OPERATING MANUAL FOR SINGLE USE MEDICAL PROTECTIVE CLOTHING
(For emergency use only for prevention and control of epidemic)

【Product Name】Single Use Medical Protective Clothing, hereinafter referred to as "protective clothing".
【Model, Size】Model: One piece overall  
Sizes: 160, 165, 170, 175, 180, 185

【Scope of Application】Provides barrier and protection to medical personnel in work with contact with blood, body fluids, secretions, etc. of potentially infectious patients.

【Product Performance】This product complies with GB 19082-2009 technical requirements for disposable protective clothing for medical use [Excludes 4.2 structure, 4.3 Model and specifications, 4.6 Breaking elongation rate 4.8 flame retardant performance, 4.10 electrostatic attenuation property, 4.11 skin irritation, 4.12.2 asepsis (not applicable) and 4.13 ethylene oxide residue (not applicable)].

【Material】Protective clothing is made of laminated spun bond non-woven fabric.

【Main Structural Components】The product consists of a hooded top and pants.

【Contraindications】No known contraindications found.

【InSTRUCTIONS】
1. Take out protective clothing  
   Tear open the outside packing and remove the protective clothing.
2. Wear protective clothing  
The order of wearing one-piece protective clothing is to wear pants first, then top and hood, finally zip up the zipper.
3. Remove protective clothing  
   First pull-down zipper to the bottom of the protective clothing (see sketch 1). Lift the hood upwards off the head then take off sleeves (see sketches 2 & 3). Roll off the clothing from top to bottom (see sketch 4). Roll inward the contaminated side until the clothing is completely removed then put the clothing into the medical waste bag (see sketch 5).

【Storage Requirements】The protective clothing package should be stored in a clean room with a relative humidity of not more than 80% and well-ventilated environment with no corrosive gases.

【Transportation Requirements】The transportation process should be performed in accordance with the contract's provisions. Avoid heavy pressure deformation, direct sunlight, hard objects scratching and rain or snow or liquid leaching.

【Precautions, Warnings & Tips】
1. The product is for single use, it is forbidden to reuse.
2. Please check the protective clothing for damage before wearing; the sleeves should not touch the face and collar when wearing. Replace a new one immediately if leakage or damaged is found. Please take precaution to avoid contamination when taking off.
3. The protective clothing is limited to put on and take off in the prescribed area.
4. The protective clothing can be used continuously when medical workers contact multiple patients with similar infectious diseases. In contact with suspected patients, the protective clothing should be changed between each patient.
5. When protective clothing is contaminated by patient's blood, body fluids and dirt, it should be replaced in time.
6. The breaking elongation rate, antistatic property, and flame retardant performance of the product have not been verified.

【Symbol】  
2) Do not reuse  
1) Refer to the operating manual  
3) Do not use if package is damaged

【Manufacture Date】See product small packaging for details  
【Revision Date of Operating Manual】2020 March 11

【Expiry Period】Six months from the date of production, see product small packaging for details.

MADE IN CHINA

Registarant / Manufacturer / After Sales Service: Zhejiang Stage Leather Apparel Co., Ltd.  
Address: Jinxi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.

Production address: Inside Zhejiang Stage Leather Apparel Co., Ltd.  
1 & 3/F, Block 2, Jinxi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.

Medical Device Production License Number: 浙械注准 20200038 号
Medical Device Registration Certificate Number: 浙械注准 20202141041

Barbara Hung +86 13777423388  
barbara@stageleather.com

02 April 2020
Form a complete set with our **Boot Cover**
(order separately)

Covering the entire foot in protection to keep out dust, grease, germs, dirt, blood, body fluid and secretion of potentially infectious patients.

**Material & Construction**
Outer layer 30g breathable laminate film
Inner layer 30g PP nonwoven fabric + 3g glue
Same as our protective clothing.

**Features**
- Boots cover are composed of flash spun high density polyethylene, providing an ideal balance of protection, durability and comfort;
- Breathable, lightweight and flexible material for exceptional wearer comfort;
- Taped seams provide additional protection;
- Excellent barrier against fine particles, protection against infectious diseases;
- Elastic top for easy wearing;
- Anti-static & Anti skid properties.

02 April 2020
Barbara Hung +86 13777423388
barbara@stageleather.com
About Factory

Manufacturer:
Zhejiang Stage Leather Apparel Co., Ltd.
Manufacture Address:
Jinxi Development Zone, Jinhua City, Zhejiang Province, China.
Business License - Disposable Protective Clothing

02 April 2020

Barbara Hung +86 13777423388
barbara@stageleather.com
BUSINESS LICENSE
(Duplicate)

Uniform Social Credit Code: 913307007580889742 (1/1)

Business Name: Zhejiang Stage Leather Apparel Company Limited

Business Type: Limited Liability Company (Sole proprietorship in Hong Kong, Macao and Taiwan)

Legal Representative: TONG YONG MEI

Business Scope: General Project: Leather apparel and products, apparel & bags production; Import and export business of the above products (excluding importing products, distribution business); Production and sales of face masks (non-medical), Sales of medical mask, Product and sales of medical devices of class I, Sales of medical devices of class II sales (except for projects subject to approval according to law, carry out business activities independently according to law with a management license). Licensed Projects: Medical mask production; Production of class II medical devices (Any projects that needs to be approved by law, can only be carried out after getting approval by relevant authorities. The specific projects are subject to the approval results).

Registered capital: One Million Five Hundred and Ten Thousand US Dollars Only

Date of Establishment: 2004 February 16

Operation Period: 2004 February 16 to 2026 February 15

Address: Jinxin Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.

Registration Authority: Jinhua Market Regulatory Administration

Date: 2020 February 25

Scan the QR code and log in to the National Enterprise Information Publicity System to learn more about registration, filing, licensing, business information.

284x68 The Market entities should submit public annual reports through the national credit publicity system from January 1 to June 30 each year.

Produced by the National Market Supervision Administration

02 April 2020 Barbara Hung +86 13777423388 barbara@stageleather.com
营业执照

名称：新德集团有限公司

注册资本：伍仟万元整

成立日期：2013年03月18日

营业期限：2013年03月18日至2043年03月17日

经营范围：一般项目：服装服饰批发；服装服饰零售；房地产经纪；房地产咨询；销售代理；企业管理；软件开发；广告设计、代理；新兴能源技术研发；日用品（非食用）销售；医用口罩零售；医用口罩批发；第一类医疗器械零售；第一类医疗器械销售；第二类医疗器械零售；第二类医疗器械销售（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）。许可项目：货物进出口；技术进出口（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，具体经营项目以审批结果为准）。

住所：浙江省金华市婺城区李渔路1103号宝龙广场A幢1801室

登记机关：2020年03月2日
BUSINESS LICENSE (Duplicate)

Business Name: Stage Group Company Limited

Business Type: Limited Liability Company (Natural investor or holding)

Legal Representative: LIU HONG JUN

Registered capital: Fifty Million Only

Date of Establishment: 2013 March 18

Operation Period: 2013 March 18 to 2043 March 17

Address: Room 1801, Block A, Baolian Square, 1103 Liyu Road, Wucheng District, Jinhua City, Zhejiang Province.

Registration Authority: Jinhua Market Regulatory Administration

Date: 2020 March 12

Business Scope: General Project: Wholesale of clothing and apparel; Retail of clothing and apparel; Real estate brokers; Real estate consulting; Sales agents; Enterprise management; Software development; Advertising design and agency; Research and development of emerging energy technologies; Sales of daily face masks (non-medical); Retail of medical face masks; Wholesale of medical face masks; Retail of Class I Medical Devices; Sales of Class I Medical Devices; Retail of Class II Medical Devices; Sales of Class II Medical Devices (except for projects that are subject to approval in accordance with the law, conduct business activities independently by virtue of law of its business license). Licensed projects: Import and export of goods; import and export of technology (projects that are subject to approval in accordance with the law, can only be operated with the approval of relevant departments, and specific operating projects are subject to the approval results).
Medical Device Production License

许可证编号： 浙食药监械生产许 20200038 号

企业名称： 浙江实皮革服饰有限公司

生产地址： 浙江省金华市婺城区汤溪镇金西经济开发区

法定代表人： 重鸣梅

生产范围： II类:14-14-医护人员防护用品，

企业负责人： 重鸣梅

住所： 浙江省金华市婺城区汤溪镇金西经济开发区

发证部门： 浙江省药品监督管理局

发证日期： 2020年3月26日

有效期限：至 2020年9月11日

国家食品药品监督管理总局制

02 April 2020

Barbara Hung +86 13777423388
barbara@stageleather.com
Name of Enterprise: Zhejiang Stage Leather Apparel Co., Ltd.

Legal Representative: TONG YONG MEI

Business Principal: TONG YONG MEI

Address: Jinxi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.

License Number: 浙食药监械生产许 20200038

Production Address: Inside Zhejiang Stage Leather Apparel Co., Ltd. Block 2, Jinxi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.

Production Range: Class II: 14-14 Medical staff protective equipment

Issuing Department: Zhejiang Medical Products Administration

Issuing Date: 2020 March 26

Produced by National Food and Medical Products Administration

02 April 2020
Barbara Hung +86 13777423388
barbara@stageleather.com
### People’s Republic of China Medical Device Registration Certificate

<table>
<thead>
<tr>
<th>Registration Certificate Number</th>
<th>浙械注准20202141041</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registrant Name</td>
<td>Zhejiang Stage Leather Apparel Co., Ltd.</td>
</tr>
<tr>
<td>Registrant Address</td>
<td>Jinxi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.</td>
</tr>
<tr>
<td>Production Address</td>
<td>Jinxi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua City, Zhejiang Province.</td>
</tr>
<tr>
<td>Agent Name</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Agent Address</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Product Name</td>
<td>Single Use Medical Protective Clothing</td>
</tr>
<tr>
<td>Model, Specification</td>
<td>Model: One Piece Coverall; Specification: 160, 165, 170, 175, 180, 185</td>
</tr>
<tr>
<td>Structure &amp; Component</td>
<td>The product is one piece coverall consists of a hooded top and pants.</td>
</tr>
<tr>
<td>Scope of Application</td>
<td>Provides barrier and protection to medical staffs in work with contact with blood, body fluids, secretions, etc. of potentially infectious patients.</td>
</tr>
<tr>
<td>Annex</td>
<td>This product complies with GB 19082-2009 technical requirements for disposable protective clothing for medical use (Excludes 4.2 structure, 4.3 Model and specifications, 4.6 Breaking elongation rate 4.8 flame retardant performance, 4.10 electrostatic attenuation property, 4.11 skin irritation, 4.12.2 asepsis (not applicable) and 4.13 ethylene oxide residues (not applicable)).</td>
</tr>
<tr>
<td>Others</td>
<td>/</td>
</tr>
<tr>
<td>Remark</td>
<td>This product is an emergency approval product for the prevention and control of pneumonia by new coronavirus infection. The registration certificate is valid for 6 months, product label and instructions should be clearly marked with “For Emergency Use only for Prevention and Control of Epidemic”.</td>
</tr>
</tbody>
</table>

**Approval Department:** Zhejiang Medical Products Administration  
**Approval Date:** 2020 March 06  
**Expiry Date:** 2020 September 05
FDA Owner/Operator# 10062956

The 3rd Party Certificate of
FDA Medical Device Registration

Establishment:
ZHEJIANG STAGE LEATHER APPAREL CO., LTD
Jixi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua, Zhejiang Province, CHINA 321000
Registration Number / FEI Number*: 10062956
Status: Active
Date of Registration Status: 2020
Owner/Operator:
ZHEJIANG STAGE LEATHER APPAREL CO., LTD
Jixi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua, Zhejiang Province, CHINA 321000
Owner/Operator Number: 10062956
Official Correspondent:
Contact Name: US JU MANAGER
Jixi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua, Zhejiang Province, CHINA 321000
Tel: +86-0575-87359393 E-mail: julied@stageleather.com
U.S. Agent:
Contact Name: Grace Liu
Address: 839 F W 1489 Road, Brookshire, Texas 77423 USA
Phone: (281) 860-8207 E-mail: grace.liu@titus.com

CE Declaration of Conformity 2017/745

Barbara Hung +86 13777423388
barbara@stageleather.com

Declaration of Conformity

Manufacturer:
Name: ZHEJIANG STAGE LEATHER APPAREL CO., LTD
Add: Jixi Economic Development Zone, Tangxi Town, Wucheng District, Jinhua, Zhejiang Province.

Product Name: SINGLE USE PROTECTIVE FACE MASK SINGLE USE MEDICAL FACE MASK

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.

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

Proprietary Name | Product Codes | Device Class | Listing Number | Establishment Operations
---|---|---|---|---
Mask | LYU | 1 | D37**** | Manufacturer
MEDICAL PROTECTIVE OVERSUIT | OEA | 1 | D37**** | Manufacturer
PROTECTIVE CLOTHING | OEA | 1 | D37**** | Manufacturer

European Representative:
Name: Careteckion GmbH
Adresse: Niederheinestr 71, 40474 Düsseldorf, Germany,
Tel: +49 211 3003 6618
Fax: +49 211 3003 6619
E-mail: info@careteckion.de

Manufacturer:

date: 2020-03-27

02 April 2020
## Certificate of EO Sterilization

**Certificate of EO Sterilization**

<table>
<thead>
<tr>
<th>Date</th>
<th>02 April 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Barbara Hung</td>
</tr>
<tr>
<td>Phone</td>
<td>+86 13777423388</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:barbara@stageleather.com">barbara@stageleather.com</a></td>
</tr>
</tbody>
</table>

---

### Technical Details

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>Protective Clothing</td>
</tr>
<tr>
<td>Model</td>
<td>Y01</td>
</tr>
<tr>
<td>Date of Sterilization</td>
<td>2020-05-16</td>
</tr>
<tr>
<td>Sterilization Date</td>
<td>20200316</td>
</tr>
<tr>
<td>Sterilization Grade</td>
<td>Class B</td>
</tr>
<tr>
<td>Sterility Date</td>
<td>20200316</td>
</tr>
<tr>
<td>Sterility Test Quantity</td>
<td>19 Pieces</td>
</tr>
<tr>
<td>Sterility Test Item</td>
<td>BI Sterilization</td>
</tr>
<tr>
<td>Sterility Test Date</td>
<td>2020-03-17-2020-03-18</td>
</tr>
<tr>
<td>Sterility Test Type</td>
<td>BI Sterilization</td>
</tr>
<tr>
<td>Sterility Test Result</td>
<td>Passed</td>
</tr>
<tr>
<td>Sterility Test Result Type</td>
<td>BI Sterilization</td>
</tr>
<tr>
<td>Sterility Test Method</td>
<td>Test Record &amp; Result</td>
</tr>
<tr>
<td>Sterility Test Result</td>
<td>BI Sterilization</td>
</tr>
<tr>
<td>Sterility Test Method</td>
<td>Test Record &amp; Result</td>
</tr>
</tbody>
</table>

---

### Biological Indicators Sterility Testing Record

<table>
<thead>
<tr>
<th>Biological Indicators Sterility Testing Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI Sterilization</td>
</tr>
<tr>
<td>Test Method:</td>
</tr>
<tr>
<td>Direct inoculation, View and Record Everyday</td>
</tr>
<tr>
<td>Test Method:</td>
</tr>
<tr>
<td>Direct inoculation, View and Record Everyday</td>
</tr>
</tbody>
</table>

---

### Conclusion

The results showed that the above products were sterilized by conventional ethylene oxide, and the biological parameters were qualified, the sterility level was guaranteed 10-4, and the BI culture value was not up to the requirement.
Test Report

Report No.: Z20200473 & Z20200585

Name of Product: Medical Protective Clothing
Specification: One piece coverall type 185
Client: Zhejiang Stage Leather Apparel Co., Ltd.
Test category: Entrusted inspection

By ZHEJIANG INSTITUTE OF MEDICAL DEVICE
SUPERVISION AND TESTING

Total 9 pages
## Test report

**Report No.:** Z20200473  
**Page 2 of 6**

### Sample Information

<table>
<thead>
<tr>
<th>Sample name</th>
<th>Medical protective clothing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specification</td>
<td>One piece coverall 185</td>
</tr>
<tr>
<td>Test category</td>
<td>Commissioned Test</td>
</tr>
<tr>
<td>Principal/unit</td>
<td>Zhejiang Stage Leather Apparel Co., Ltd.</td>
</tr>
<tr>
<td>Name of the client</td>
<td>Zhejiang Stage Leather Apparel Co., Ltd.</td>
</tr>
<tr>
<td>Name of manufacturing unit</td>
<td>Zhejiang Stage Leather Apparel Co., Ltd.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sampling method</th>
<th>Sample presentation</th>
<th>Sampling location</th>
<th>/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling date</td>
<td>/</td>
<td>Sampling base</td>
<td>/</td>
</tr>
<tr>
<td>Sample person</td>
<td>/</td>
<td>Sample acceptance date</td>
<td>2020-02-03</td>
</tr>
<tr>
<td>Sample size</td>
<td>13 packs</td>
<td>Sample production date</td>
<td>2020.02.22</td>
</tr>
<tr>
<td>Sample lot/number</td>
<td>20200202</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Test basis       | GB 19082-2009       |
| Test item        | All projects (except 4.2, 4.3, 4.6, 4.8, 4.10, 4.11, 4.12.2, 4.13) |
| Test date        | February 23, 2020-March 07, 2020 |

---

### Test Methods

- **Subcontracting Test items:** /  
- **Test site:** Ningbo laboratory  
- **Client/Company Information:**  
  - **Telephone:** 0579-82377299  
  - **Postcode:** /  
  - **Address:** Tang Xi Zhen Jin Xi Development Zone, Wucheng District, Jinhua City, Zhejiang Province  

### Test Methods Adopted

- Standard methods:   
- Method of customer customization:   
- Methods provided by our laboratory:   
- Other methods:   

### Statement/Information for Evaluating Uncertainty of Measurement

/  

### Comments and explanations

/  

### Sample description

Sample status description:
- a) Structural composition:   
- b) Principle, purpose:   
- c) Main characteristic parameters: appearance, water permeability, moisture permeability, synthetic blood resistance, surface moisture resistance, breaking strength, filtration efficiency, antistatic property and microbial limit:   
- d) Sample status: intact.  

### Other instructions

1. This product is of a linked structure; 2. "4.11 skin irritation" is mandatory and has not been tested.
### Summary of test results

**Report No.: Z20200473**

#### Page 3 of 6

<table>
<thead>
<tr>
<th>No.</th>
<th>Test item</th>
<th>Standard Clause</th>
<th>Standard requirements</th>
<th>Measured results</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Appearance</td>
<td>4.1.1</td>
<td>Protective clothing should be dry, clean and free from mildew.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.1</td>
<td>No adhesion, cracks, holes and other defects are allowed on the surface.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>Connection parts of protective clothing can be processed by sewing, bonding or heat sealing, etc.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>The eye of the needle should be sealed</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>The stitches shall be uniform and straight, and there shall be no jumping needles.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>After processing such as bonding or heat sealing, the parts shall be flat, sealed and free of bubbles.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.3</td>
<td>Zipppers of protective clothing equipped with zipppers shall not be exposed.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.3</td>
<td>The slider should be self-locking.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td>2</td>
<td>Liquid permeability resistance</td>
<td>4.4.1</td>
<td>Hydrostatic pressure of key parts of protective clothing shall not be less than 1.67kPa(17cmH₂O)</td>
<td>15.46kPa</td>
<td>Pass</td>
</tr>
<tr>
<td>3</td>
<td>Moisture Permeability</td>
<td>4.4.2</td>
<td>The moisture permeability of protective clothing materials (outside) shall not be less than 2500 g/(m² d)</td>
<td>4440</td>
<td>Pass</td>
</tr>
<tr>
<td>4</td>
<td>Synthetic Blood Penetration Resistance</td>
<td>4.4.3</td>
<td>The anti-synthetic blood penetration of protective clothing shall not be lower than the requirements of Level 2 in Table 3.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td>5</td>
<td>Surface Moisture Resistance</td>
<td>4.4.4</td>
<td>The water level on the outer side of the protection unit shall not be lower than the requirement of level 3.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td>No.</td>
<td>Test item</td>
<td>Standard Clause</td>
<td>Standard requirements</td>
<td>Measured results</td>
<td>Conclusion</td>
</tr>
<tr>
<td>-----</td>
<td>------------------</td>
<td>-----------------</td>
<td>------------------------</td>
<td>------------------</td>
<td>------------</td>
</tr>
<tr>
<td>6</td>
<td>Tensile Strength</td>
<td>4.5</td>
<td>The breaking strength of material (longitudinal) at key parts of protective clothing shall not be less than 45N.</td>
<td>128</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The breaking strength of materials (transverse) at key parts of protective clothing shall not be less than 45KN.</td>
<td>53</td>
<td>Pass</td>
</tr>
<tr>
<td>7</td>
<td>Filtration efficiency</td>
<td>4.7</td>
<td>The filtration efficiency of materials in key parts of protective clothing for non-oily particles shall not be less than 70%</td>
<td>99.95% ~ 99.98%</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The filtration efficiency of non-oily particles at joints of key parts of protective clothing shall not be less than 70%</td>
<td>99.97% ~ 100%</td>
<td>Pass</td>
</tr>
<tr>
<td>8</td>
<td>Antistatic property</td>
<td>4.9</td>
<td>The electric charge of protective clothing shall not be more than 0.6μC/ piece.</td>
<td>0.1</td>
<td>Pass</td>
</tr>
<tr>
<td>9</td>
<td>Microbial limit</td>
<td>4.12.1</td>
<td>Protective clothing shall meet the requirements of microbiological indexes in GB15970-2002: bacteria ≤200CFU/g</td>
<td>&lt;20CFU/g</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Coliform: not detectable
Staphylococcus aureus: Not Detectable
Hemolytic streptococcus: not detectable
Total number of fungal colonies: ≤100CFU/g

This page is blank below.
**Test report**

**Sample name**: Medical protective clothing

<table>
<thead>
<tr>
<th>Specification</th>
<th>Test category</th>
<th>Commissioned Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>One piece coverall 185</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Principal/unit**: Zhejiang Stage Leather Apparel Co., Ltd.

**Name of the client**: Zhejiang Stage Leather Apparel Co., Ltd.

**Name of manufacturing unit**: Zhejiang Stage Leather Apparel Co., Ltd.

<table>
<thead>
<tr>
<th>Sampling method</th>
<th>Sampling location</th>
<th>/</th>
</tr>
</thead>
<tbody>
<tr>
<td>sample presentation</td>
<td>/</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sampling date</th>
<th>Sampling base</th>
<th>/</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>/</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample person</th>
<th>Sample acceptance date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>2020-02-03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample size</th>
<th>Sample production date</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 packs</td>
<td>2020.02.22</td>
</tr>
</tbody>
</table>

**Sample lot/number**: 20200202

**Test basis**: GB 19082 -2009

**Test item**: 4.1

**Test date**: February 23, 2020-March 07, 2020

**Test conclusion**: The tested items of the tested samples meet the requirements of GB 19082-2009 "Technical Requirements for Single Use Medical Protective Clothing". Special Seal for Test report: Special Seal for Test of ZHEJIANG INSTITUTE OF MEDICAL DEVICE SUPERVISION AND TESTING.

**Approved by**: Zhang Li
**Checked by**: Zhou Tong
**Chief Inspector**: Wang Minzhu
**Position**: Authorized signatory
**Date**: March 09, 2020
**Date**: March 07, 2020
**Date**: 2020.03.07

**Test site**: Ningbo laboratory

**Subcontracting test items**: /

**Client/Company Information**

<table>
<thead>
<tr>
<th>Telephone</th>
<th>Postcode</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>0579-82377299</td>
<td>/</td>
<td>Tang Xi Zhen Jin Xi Development Zone, Wucheng District, Jinhua City, Zhejiang Province</td>
</tr>
</tbody>
</table>

**Uncertainty of evaluation & measurement Statement / Information of Degree**: /

**Comments and explanations**: /

**Sample status description**: A) structural composition; B) principle and purpose; C) main characteristic parameters: appearance D) sample status: intact.

**Other instructions**: 1. This product is of a linked structure, 2.4.4.1 has water permeability resistance, 4.4.2 moisture permeability and 4.4.3 synthetic blood permeability resistance. 4.4.4 Surface moisture resistance, 4.5 breaking strength, 4.7 filtration efficiency, 4.9 antistatic property, 4.11 skin irritation and 4.12.1 microbial limit "are mandatory requirements and have not been tested.

**02 April 2020**
## Summary of test results

<table>
<thead>
<tr>
<th>No.</th>
<th>Test item</th>
<th>Standard clause</th>
<th>Standard requirements</th>
<th>Measured results</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Appearance</td>
<td>4.1.1</td>
<td>Protective clothing should be dry, clean and free from mildew.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.1</td>
<td>No adhesion, cracks, holes and other defects are allowed on the surface.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.1</td>
<td>Connection parts of protective clothing can be processed by sewing, bonding or heat sealing, etc.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>The eye of the needle should be sealed</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>Needle spacing should be 8 ~14 needles per 3cm</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>The stitches shall be uniform and straight, and there shall be no jumping needles.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.2</td>
<td>After processing such as bonding or heat sealing, the parts shall be flat, sealed and free of bubbles.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.3</td>
<td>Zippers of protective clothing equipped with zippers shall not be exposed.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1.4</td>
<td>The slider should be self-locking.</td>
<td>Satisfied</td>
<td>Pass</td>
</tr>
</tbody>
</table>

This page is blank below.
## Carton Label

<table>
<thead>
<tr>
<th>Specification Color</th>
<th>160</th>
<th>165</th>
<th>170</th>
<th>175</th>
<th>180</th>
<th>185</th>
<th>Total quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid white</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50 pieces</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Net weight</th>
<th>13.5 KGS</th>
<th>Gross weight</th>
<th>15 KGS</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Carton</th>
<th>56×35×60 cm</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Box number/total box number</th>
<th>Box () of boxes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Registered Person/Production Enterprise</th>
<th>Zhejiang Stage Leather Apparel Co., Ltd.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Production license number</th>
<th>浙食药监械生产许 20200038</th>
<th>Registration number</th>
<th>Zhejiang Machinery Injection Standard 20202141041</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Production enterprise</th>
<th>Tang Xi Zhen Jin Xi Development Zone, Wucheng District District, Jinhua City, Zhejiang Province</th>
</tr>
</thead>
</table>
Factory Workshop
Packaging

50 pcs per carton

Carton Dimension
56L x 35W x 60H cm

Carton Weight
NW 13.5kg  GW 15kg
OUR ADVANTAGES

1. Customer Service: 24/7

2. Competitive price

3. High-quality assurance: FDA certified & CE certified

4. The packing is water-proof, damp-proof & sealed in plastic bag.

5. Over 20 years of experience in import export & international trade; Provides assistance in China custom clearance.