

# Surgical Gown

# Brief introduction

In surgical operations, the medical staff as well as patients must be reliably protected irrespective of the procedure. [Surgical gowns play an important part in eliminating routes of infection through the provision of safe, disposable products.](#)

As a professional manufacturer, we provide sterile surgical gown, made out of SMS, SMMS and Spunlace material which are very light and ensures high resistance against liquids and bacteria penetration and tensile strength, in compliance with high European standards EN13795. The sterile surgical gown is completely seamless.





# Surgical Gown

Meet the performances as follows:

- Resistance to liquid penetration and pathogens
- Bursting strength& Tensile strength standards
- Antistatic property
- Breathable and comfortable
- Ideal for surgery procedures to provide all-over protection for the patient and the surgical team.

# Products types

## N306-U1 Standard surgical gown

Without reinforcement

With basic resistance to penetration by fluids and bacteria, good microbial barrier

Applications: for **minor procedures involving slight quantities of fluid**



## N306-U3 Reinforced surgical gown

Reinforced at chest and half sleeves

Strong water resistance especially on critical area, good microbial barrier

Applications: for protection during operations involving **medium or large quantities of fluids.**



# Advance Ultrasonic Sealing

## Traditional Sealing



## Ultrasonic Thermal Sealing



Thanks to our Clean Room, we could be capable of manufacturing and offering a full range of disposable products to satisfy all needs of cutting-edge operating rooms.

The sterile surgical gown is **completely seamless**.

Our advance Ultrasonic Thermal Sealing assures stronger barrier and higher security. As a matter of fact, to stitch a fabric it is necessary to pierce the fabric in order to let the yarn pass through: these micro holes can be easily penetrated by liquids and bacteria. **Our thermal sealing the edges are overlapped and sealed through the ultrasonic heating, therefore there is no perforation nor tears so that even this potential risk is avoid.**

# Special attention on every details

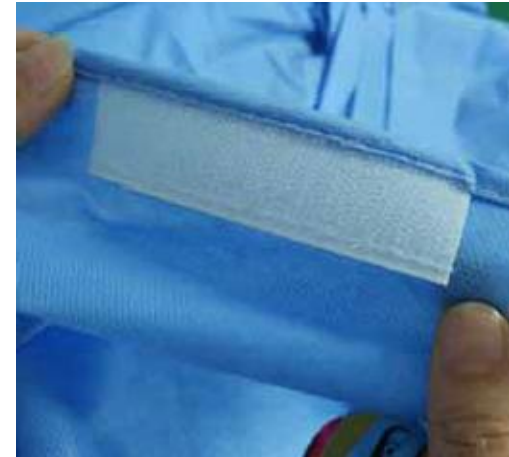
**7cm cotton cuff  
(instead of knitted cuff)**



**Ultrasonic tie**



**Extra-long velcro**



We pay every attention on the surgical gown quality. Every detail is designed for the comfortable and convenient wearing of end users.

Our workers are skillful and trained well, working strictly to the clean room work regulation.

**They only produce surgical gown**, have rich experience and very skillful hand working

The quality is well approved by European customers.

# Special attention on every details

**Paper card**  
(fixing the ties)



**Hand towel**



**SMS wrapping+  
Paper pouch**



All the accessories are requested in high quality, 100% inspected by our QC dept..



# Efficiency Folding Method

All our surgical gown is folded in professional surgical way.

This folding way is designed for surgical gown, which is easy for doctor's wearing



Surgical Gown Folding Method





# Quality Assurance



## Environment- Health, Safety & Clean

ISO-certified clean room with a unique environment with strict controls for dust, room pressure and temperature, and other variables, which ensure to protect surgical gowns or packs from contaminants.



# Quality Assurance

## Work Flow

### Lean Manufacturing Principles

8.1 In-Process QC



Clean Room



1. Material



2. Platemaking



3.1 Fabric Cutting



3.2 Fabric Cutting



7. Packing



6. Folding



5. Sewing



4. Sewing



8.2 QC- Final Inspection



9. Sterilizing



10. Storage



11. Loading



# Quality Assurance

## Raw materials quality control

### ● Inspection Record for Hydrohead Pressure

**原材料检验报告**

原料编码: 47, SMS 供货商: 山恒天嘉华 批号:

| 次数                          | 1  | 2    | 3     | 4    | 5     | 6    | 7    | 8    | 9    | 10   | 平均值  | STD  |
|-----------------------------|----|------|-------|------|-------|------|------|------|------|------|------|------|
| 卷号                          | 47 | 44   | 46    | 45   | 46    | 46   | 47   | 47   | 48   | 48   | 46.4 |      |
| 单重(g)                       |    |      |       |      |       |      |      |      |      |      |      |      |
| 剥离强力<br>(LB/1")             | CD |      |       |      |       |      |      |      |      |      |      |      |
|                             | MD |      |       |      |       |      |      |      |      |      |      |      |
| 断裂伸长<br>(mm)                | CD |      |       |      |       |      |      |      |      |      |      |      |
|                             | MD |      |       |      |       |      |      |      |      |      |      |      |
| 厚度(mm)                      |    |      |       |      |       |      |      |      |      |      |      |      |
| 静水压<br>(cmH <sub>2</sub> O) |    | 63.6 | 68.11 | 67.9 | 66.15 | 60.2 | 65.3 | 64.1 | 69.7 | 60.2 | 61.2 | 62.6 |
| 剥离强力<br>(LB/1")             | CD |      |       |      |       |      |      |      |      |      |      |      |
|                             | MD |      |       |      |       |      |      |      |      |      |      |      |
| 透气率                         |    |      |       |      |       |      |      |      |      |      |      |      |

### ● Inspection Record for Tensile Strength

47G-SMS-纵向 织物拉伸测试报告

| 序号     | 断裂强力<br>F <sub>m</sub> | 断裂伸长<br>E <sub>m</sub> | 断裂强力<br>F <sub>b</sub> | 断裂伸长<br>E <sub>b</sub> | 断裂强力<br>F <sub>t</sub> | 断裂伸长<br>E <sub>t</sub> | 断裂强力<br>F <sub>c</sub> | 断裂伸长<br>E <sub>c</sub> | 断裂强力<br>F <sub>s</sub> | 断裂伸长<br>E <sub>s</sub> | 断裂强力<br>F <sub>u</sub> | 断裂伸长<br>E <sub>u</sub> |
|--------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| 1      | 65.50                  | 1.11                   | 75.83                  | 70.22                  | 62.63                  | 3721.86                | 5.52                   | 88.1                   | 89.1                   | 2866.52                | 65.50                  |                        |
| 2      | 61.14                  | 1.22                   | 73.52                  | 73.2                   | 64.38                  | 2276.27                | 5.52                   | 95.34                  | 95.34                  | 2725.61                | 61.14                  |                        |
| 3      | 68.02                  | 1.36                   | 82.31                  | 82.15                  | 69.53                  | 6125.89                | 5.52                   | 100.09                 | 100.09                 | 4089.20                | 68.02                  |                        |
| 4      | 64.02                  | 1.29                   | 66.81                  | 65.13                  | 53.28                  | 4195.35                | 5.71                   | 84.3                   | 84.3                   | 4415.90                | 64.02                  |                        |
| 5      | 68.17                  | 1.36                   | 76.36                  | 75.89                  | 67.69                  | 3963.14                | 5.91                   | 91.67                  | 91.67                  | 4497.84                | 68.17                  |                        |
| 6      | 68.69                  | 1.36                   | 76.65                  | 75.75                  | 65.86                  | 3615.30                | 5.52                   | 96.22                  | 96.22                  | 4655.62                | 68.69                  |                        |
| 7      | 63.92                  | 1.29                   | 63.60                  | 62.81                  | 58.52                  | 2926.30                | 5.52                   | 76.29                  | 76.29                  | 3455.66                | 63.92                  |                        |
| 8      | 64.89                  | 1.29                   | 69.11                  | 68.1                   | 61.76                  | 3269.79                | 5.62                   | 85.14                  | 85.14                  | 3919.53                | 64.89                  |                        |
| 9      | 64.75                  | 1.29                   | 76.78                  | 76.34                  | 66.61                  | 3665.50                | 5.64                   | 90                     | 90                     | 4066.23                | 64.75                  |                        |
| 10     | 59.90                  | 1.2                    | 69.67                  | 68.28                  | 62.65                  | 2992.97                | 5.92                   | 82.78                  | 83.78                  | 3392.38                | 59.90                  |                        |
| 最大值    | 68.17                  | 1.36                   | 88.61                  | 85.15                  | 73.28                  | 6125.89                | 5.71                   | 100.09                 | 100.09                 | 4689.20                | 68.17                  |                        |
| 最小值    | 59.90                  | 1.20                   | 63.60                  | 62.81                  | 58.52                  | 2926.30                | 5.61                   | 76.29                  | 76.29                  | 3392.38                | 59.90                  |                        |
| 平均值    | 64.80                  | 1.29                   | 74.71                  | 75.19                  | 65.23                  | 3746.14                | 5.59                   | 89.79                  | 89.79                  | 4054.89                | 64.80                  |                        |
| CV值(%) | 8.33                   | 6.31                   | 9.37                   | 9.38                   | 9.58                   | 11.62                  | 4.28                   | 5.18                   | 7.22                   | 11.52                  | 4.33                   |                        |

检测日期: 2017年03月03日





## 湖北乐信医疗用品有限公司

### 车间巡检记录

文件编号: LSH-20-06-20201117
版本: V2.1
No. 201703

|      |          |     |              |      |              |
|------|----------|-----|--------------|------|--------------|
| 生产序号 | 188      | 设备号 | LXH-20170301 | 型号   | LXH-20170301 |
| 日期   | 2017.3.1 | 巡检员 | 张华           | 审核日期 | 2017.3.1     |

| 序号   | 工序名称 | 设备编号 | 检查结果       | 结论 |
|------|------|------|------------|----|
| ① 机壳 | 05   | XL   | 尺寸 15.10mm | 合格 |
|      | 09   | XL   | 尺寸 15.10mm | 合格 |
|      | 07   | XL   | 尺寸 15.10mm | 合格 |
|      | 11   | XL   | 尺寸 15.10mm | 合格 |
|      | 10   | XL   | 尺寸 15.10mm | 合格 |
|      | 09   | XL   | 尺寸 15.10mm | 合格 |
|      | 16   | XL   | 尺寸 15.10mm | 合格 |
|      | 15   | XL   | 尺寸 15.10mm | 合格 |
|      | 20   | XL   | 尺寸 15.10mm | 合格 |
|      | 27   | XL   | 尺寸 15.10mm | 合格 |
| ② 机壳 | 17   | XL   | 尺寸 15.10mm | 合格 |
|      | 14   | XL   | 尺寸 15.10mm | 合格 |
|      | 16   | XL   | 尺寸 15.10mm | 合格 |
|      | 17   | XL   | 尺寸 15.10mm | 合格 |
| ③ 机壳 | 30   | XL   | 尺寸 15.10mm | 合格 |
|      | 31   | XL   | 尺寸 15.10mm | 合格 |

巡检人: 张华

日期: 2017.3.1

说明: 每片产品抽检 10 片, 抽检合格率为 100% 以上, 方可投入生产。每片产品抽检 10 片, 抽检合格率为 100% 以上, 方可投入生产。抽检不合格率 10% 以上, 停止生产, 查明原因, 整改合格后方可继续生产。

# Quality Assurance

## Inspection Record for Pouch Sealing

**湖北乐信医疗用品有限公司**  
**产品包装封口检验记录**

文件编号: LBL-SQ22-06-20181117 版本: V2.1 No.

|      |             |      |             |      |     |
|------|-------------|------|-------------|------|-----|
| 订单号  | 11000-10115 | 生产单号 | 100         | 产品型号 | 100 |
| 设备编号 | 02          | 检验日期 | 2017年10月10日 | 检验员  | 刘佳  |
| 封口袋数 | 260         | 封口温度 | 260℃        | 封口速度 |     |

**封口前确认记录**



| 设备名称           | 设备编号             | 封口温度                | 封口速度          | 封口压力             | 封口时间         | 签名        | 日期   |
|----------------|------------------|---------------------|---------------|------------------|--------------|-----------|------|
| Equipment Name | Equipment Number | Sealing Temperature | Sealing Speed | Sealing Pressure | Sealing Time | Signature | Date |
|                |                  | 260                 |               |                  | 8-15         |           | 2017 |

**Seal Test**  
**纸塑袋测试卡**

山东乐信医疗科技有限公司  
电话: 18723736750 传真: 0533-7500199  
网址: www.lxmedical.com 邮箱: lxmedical@163.com  
地址: 山东省淄博市张店区南定镇南定村

| 序号 | 封口外观 | 包装完整性 | 消毒标识/条形码确认 | 包装方式和数量/封口确认 | 检验结论 |
|----|------|-------|------------|--------------|------|
| 1  | ✓    | ✓     | ✓          | 80件/箱        | 合格   |
| 2  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 3  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 4  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 5  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 6  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 7  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 8  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 9  | ✓    | ✓     | ✓          | ✓            | 合格   |
| 10 | ✓    | ✓     | ✓          | ✓            | 合格   |

发现人: 刘佳

说明: 按照上午下午两个班次进行抽检, 封口过程每班次抽检10件, 装箱过程每班次抽检10箱

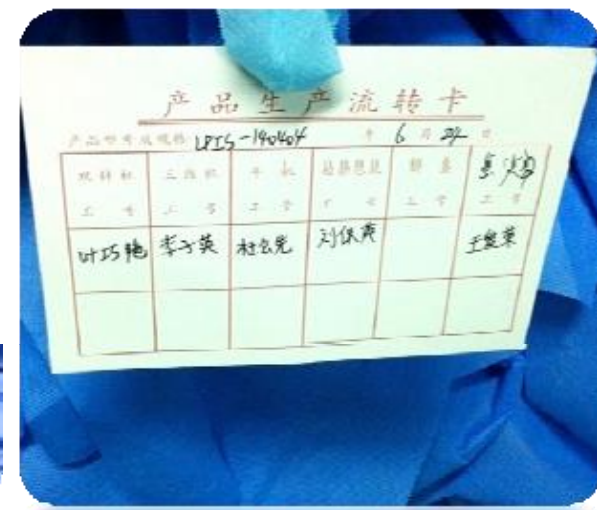


Inspection Record for pouch sealing

# Quality Assurance

## Quality Control

- Strictly Tracing System - Strictly carry out Incoming inspection, In-Process inspection, Final inspection.
- All processes of production with strictly QC to continuously ensure the high quality of every product! Tracking
- card





# EO Sterilization

证书编号: YX20111201  
Report No: YX20111201

## 环氧乙烷灭菌证明

### CERTIFICATE OF EO STERILIZATION

客户名称(Customer): Lufan Healthcare Products Limited  
灭菌日期(STERILIZATION DATE): 16/12/2011  
产品(PRODUCT): 客户证实用与手术套(套型: ENG) 数量: 600 件  
数量 QUANTITY: 12 cartons

| 环氧乙烷灭菌工艺验证报告  |   |           |
|---|---|-----------|
| Ethylene oxide sterilization process validation reports |   |           |
| 验证目的:<br>Verification purpose                           | 环氧乙烷灭菌工艺验证, 确认11号灭菌设备灭菌工艺符合产品的要求<br>Ethylene oxide sterilization process validation confirming the current sterilization equipment and sterilization process is fine with the requirements of product |           |
| 灭菌工艺:<br>Sterilization process                          | 灭菌参数 Sterilization Parameters   |           |
|   | 预真空压力 Pre-vacuum pressure   | -0.15 MPa |
|   | 灭菌温度 Sterilization temperature  | 40 ± 1℃   |
|   | 灭菌湿度 Sterilization humidity   | 30-80%    |
|   | 压力 Pressure   | -0.1 MPa  |
| 环氧乙烷剂量 Ethylene dosage                                  | 0.05kg/L  |           |
| 灭菌时间 Time   | 4 小时 15 分钟  |           |

此证书和产品灭菌参数及检测报告均由本公司出具, 予以证明。  
The sterilization parameters of products and testing results of the biological indicator are in strict conformity with the requirement. The products of this sterilization is allowed to release.

灭菌日期: 16/12/2011



The EO sterilization process is done by strict procedure. We have control on sterilization parameters, pre-vacuum pressure, sterilization temperature, humidity, dosage and time.

sample of sterilization failure



Sterilization success



湖北乐信医疗用品有限公司

BI 放行记录

文件编号: LB-SC17-15-2016-V2.0

版本: V2.0

| 灭菌批号     | 生产单号   | BI批号     | 培养条件     | 检验员 | 检验日期      |   |   |   |   |    |    |    |    |    |    |    |      |
|----------|--|----------|----------|-----|-----------|---|---|---|---|----|----|----|----|----|----|----|------|
| 206051A1 | 20   | 20151011 | 35℃, 48h | 何国  | 2016.6.21 |   |   |   |   |    |    |    |    |    |    |    |      |
| 检验项目     | BI编号及培养结果  |          |          |     |           |   |   |   |   |    |    |    |    |    |    |    | 阳性对照 |
|          | 1  | 2        | 3        | 4   | 5         | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |      |
| BI观察颜色   | ✓  | ✓        | ✓        | ✓   | ✓         | ✓ | ✓ | ✓ | ✓ | ✓  | ✓  | ✓  | ✓  | ✓  | ✓  | ✓  | 红    |
| BI培养结果   | -  | -        | -        | -   | -         | - | - | - | - | -  | -  | -  | -  | -  | -  | -  | 黄    |
| 说明       | 因的观察颜色由红色变成蓝色, 则在培养结果中划“/”, 未变色则划“X”<br>BI培养结果中BI的颜色为绿色, 则在培养结果中划“-”, 黄色则划“+”<br>阳性对照的BI培养结果为黄色, 其它16个BI培养结果为绿色, 则说明灭菌效果合格 |          |          |     |           |   |   |   |   |    |    |    |    |    |    |    |      |



We do BI test to ensure the sterilization of every order