REPORT NUMBER: SHAT06497575

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检测
TESTING
CNAS L0139

# TEST REPORT

Number : SHAT06497575
报告号：

Applicant : WUJANG TUTAIKE TEXTILES & FINISHING CO., LTD
申请公司： 吴江市涂泰克纺织后整理有限公司
NO. 1599, SOUTH THIRD RING, SHENGZE TOWN, WUJIANG CITY, JIANGSU PROVINCE
吴江市盛泽镇南三环 1599 号
Attn : Zhang Yanwen
联系人： 张燕文

Date : May 29, 2020
日期： 2020 年 5 月 29 日

Sample Description As Declared :
样品描述：

| | | |
|---|---|---|
| No. Of Sample<br>样品数量 | : | Seventeen (17)<br>17 件 |
| Fibre Content<br>成分 | : | - |
| Sample Name<br>样品名称 | : | SMS surgical gown<br>SMS 后扣式手术衣 |
| Finishing<br>处理 | : | - |
| End Uses<br>最终用途 | : | - |
| Colour<br>颜色 | : | Blue<br>蓝色 |
| Style No.<br>款号 | : | - |
| Order No./PO No.<br>订单号 | : | - |
| Buyer's Name<br>买家名称 | : | - |
| Manufacturer's Name<br>供应商名称 | : | Wujiang Tutaike Textile&Finishing Co., Ltd<br>吴江市涂泰克纺织后整理有限公司 |
| Ref.<br>参考 | : | - |

Prepared And Checked By:
For Intertek Testing Services Ltd.,Shanghai

Jennifer Ren
General Manager

INTERTEK TESTING SERVICES LTD., SHANGHAI 上海天祥质量技术服务有限公司 检验检测专用章



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TEST REPORT

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Applicant's Provided Care Instruction/Label : -
申请人所提供之水洗标签：-

| | | |
|---|---|---|
| Date Sample Received<br>收件日期 | : | May 13, 2020<br>2020-05-13 |
| Date Testing Started<br>测试开始日期 | : | May 15, 2020<br>2020-05-15 |
| Standard<br>标准 | : | EN 13795-1:2019 <Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns><br>EN 13795-1:2019《手术服和手术单要求和测试方法 第 1 部分：手术衣和手术单》 |
| Remark<br>备注 | : | The English Version Of This Test Report Is Standard One, The Chinese Version Is Only For Reference<br>此报告以英文为主，中文仅供参考 |

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TEST REPORT

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Conclusion:

| | |
|---|---|
| Bursting strength(dry state)[Material] | M |
| 胀破强度（干态）[面料] | 符合 |
| Bursting strength(dry state)[Sleeve seam] | M |
| 胀破强度（干态）[袖缝] | 符合 |
| Bursting strength(wet state)[Material] | M |
| 胀破强度（湿态）[面料] | 符合 |
| Bursting strength(wet state)[Sleeve seam] | M |
| 胀破强度（湿态）[袖缝] | 符合 |
| Breaking strength(dry state)[Material] | M |
| 断裂强力（干态）[面料] | 符合 |
| Breaking strength(dry state)[Sleeve seam] | M |
| 断裂强力（干态）[袖缝] | 符合 |
| Breaking strength(wet state)[Material] | M |
| 断裂强力（湿态）[面料] | 符合 |
| Breaking strength(wet state)[Sleeve seam] | M |
| 断裂强力（湿态）[袖缝] | 符合 |
| Static hydrostatic resistance[Material] | M |
| 静水压[面料] | 符合 |
| Static hydrostatic resistance[Sleeve seam] | M |
| 静水压[袖缝] | 符合 |
| Cleanliness-microorgnism | M |
| 洁净度-微生物 | 符合 |
| The resistance to dry microbial penetration[Material] | M |
| 阻干态微生物[面料] | 符合 |
| The resistance to dry microbial penetration[Sleeve seam] | M |
| 阻干态微生物[袖缝] | 符合 |
| The resistance to wet bacterial penetration[Material] | M |
| 阻湿态微生物[面料] | 符合 |
| The resistance to wet bacterial penetration[Sleeve seam] | M |
| 阻湿态微生物[袖缝] | 符合 |
| Lint and other particles generation in the dry state[Material] | M |
| 干态落絮[面料] | 符合 |
| Lint and other particles generation in the dry state[Sleeve seam]干态落絮[袖缝] | M 符合 |

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| | |
|---|---|
| Weight Per Unit Area<br>织物克重 | - |

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment
注释："M"-符合标准要求 "F"-不符合标准要求,"---"-无结论

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TEST REPORT

Number : SHAT06497575
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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**1 Bursting strength（dry state）[Material]**
**Test Method:** EN ISO 13938-1:1999

**Test principle:**
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

**Test equipment:**
Bursting tester

**The environmental conditions of the laboratory and test condition:**
Pretreatment: Condition the test specimens at 20.1℃ air at 65.3% RH for 24 h
Test Area: 10cm²

**Results:**

| Sample | Measured value (kPa) | Requirement (kPa) | Conclusion |
|---|---|---|---|
| 1 | 150 | ≥40<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| 2 | 150 | | |
| 3 | 146 | | |
| 4 | 145 | | |
| 5 | 148 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**2 Bursting strength（dry state）[Sleeve seam]**
**Test Method:** EN ISO 13938-1:1999

**Test principle:**
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

**Test equipment:**
Bursting tester
**The environmental conditions of the laboratory and test condition:**
Pretreatment: Condition the test specimens at 20.1℃ air at 65.3% RH for 24 h
Test Area: 10cm²

**Results:**

| Sample | Measured value (kPa) | Requirement (kPa) | Conclusion |
|---|---|---|---|
| 1 | 188 | ≥40<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| 2 | 182 | | |
| 3 | 162 | | |
| 4 | 178 | | |
| 5 | 172 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**3 Bursting strength（wet state）[Material]**
**Test Method:** EN ISO 13938-1:1999

**Test principle:**
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

**Test equipment:**
Bursting tester

**The environmental conditions of the laboratory and test condition:**
Test Area: 10cm²

**Results:**

| Sample | Measured value (kPa) | Requirement (kPa) | Conclusion |
|---|---|---|---|
| 1 | 128 | ≥40<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| 2 | 158 | | |
| 3 | 134 | | |
| 4 | 142 | | |
| 5 | 146 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**4 Bursting strength（wet state）[Sleeve seam]**
**Test Method:** EN ISO 13938-1:1999

**Test principle:**
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

**Test equipment:**
Bursting tester

**The environmental conditions of the laboratory and test condition:**
Test Area: 10cm²

**Results:**

| Sample | Measured value (kPa) | Requirement (kPa) | Conclusion |
|---|---|---|---|
| 1 | 199 | ≥40<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| 2 | 170 | | |
| 3 | 152 | | |
| 4 | 168 | | |
| 5 | 177 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**5 Breaking strength（dry state）[Material]**
**Test Method:** EN 29073-3:1992

**Test principle:**
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

**Test equipment:**
Tensile testing machine

**The environmental conditions of the laboratory and test condition:**
Pretreatment: Condition the test specimens at 20.1℃ air at 65.1% RH for 24 h The distance between the clamps: 200 mm
Rate: 100 mm/min

**Results:**

| Sample | Length (N) | Width (N) | Requirement (N) | Conclusion |
|---|---|---|---|---|
| 1 | 94.7 | 50.6 | ≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019 | Pass |
| 2 | 94.1 | 50.7 | | |
| 3 | 96.8 | 50.8 | | |
| 4 | 97.8 | 48.5 | | |
| 5 | 97.7 | 47.8 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**6 Breaking strength（dry state）[Sleeve seam]**
**Test Method**: EN 29073-3:1992

**Test principle:**
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

**Test equipment:**
Tensile testing machine

**The environmental conditions of the laboratory and test condition:**
Pretreatment: Condition the test specimens at 20.1℃ air at 65.1% RH for 24 h The Distance between the clamps: 200 mm
Rate: 100 mm/min

**Results:**

| Sample | (N) | | Requirement (N) | Conclusion |
|---|---|---|---|---|
| 1 | 40.3 | | ≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019 | Pass |
| 2 | 37.1 | | | |
| 3 | 31.9 | | | |
| 4 | 32.8 | | | |
| 5 | 34.2 | | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**7 Breaking strength（wet state）[Material]**
**Test Method:** EN 29073-3:1992

**Test principle:**
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

**Test equipment:**
Tensile testing machine

**Test condition:**
The distance between the clamps: 200 mm Rate: 100 mm/min

**Results:**

| Sample | Length (N) | Width (N) | Requirement (N) | Conclusion |
|---|---|---|---|---|
| 1 | 95.7 | 45.9 | ≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019 | Pass |
| 2 | 97.3 | 46.3 | | |
| 3 | 96.1 | 46.5 | | |
| 4 | 93.0 | 46.9 | | |
| 5 | 96.9 | 50.8 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**8 Breaking strength（wet state）[Sleeve seam]**

**Test Method:** EN 29073-3:1992

**Test principle:**
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

**Test equipment:**
Tensile testing machine

**Test condition:**
The distance between the clamps: 200 mm Rate: 100 mm/min

**Results:**

| Sample | (N) | | Requirement (N) | Conclusion |
|---|---|---|---|---|
| 1 | 32.7 | | ≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019 | Pass |
| 2 | 33.8 | | | |
| 3 | 36.2 | | | |
| 4 | 32.6 | | | |
| 5 | 26.2 | | | |

Remark :Test was conducted by external provide



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**9 Static hydrostatic resistance[Material]**

**Test Method:** EN ISO 811:2018

**Test principle:**
The hydrostatic head supported by a fabric is a measure of the opposition to the passage of water through the fabric. A specimen is subjected to a steadily increasing pressure of water on one side of the fabric, under standard conditions, until penetration occurs in three places. The pressure at which the water penetrates the fabric at the third place is noted.

**Test equipment:**
Hydrostatic tester
Water, grade 3 water in accordance with ISO 3696.
The environmental conditions of the laboratory and test condition:
Pretreatment: Condition the test specimens at 20.0℃ air at 65.2% RH for 24 h Face side tested
Temperature of the water: 20.0℃
Rate of incereasing water pressure:10cm $H_2O$/min

**Results:**

| Sample | Measured value ($cmH_2O$) | Requirement ($cmH_2O$) | Conclusion |
|---|---|---|---|
| 1 | 67.0 | ≥20<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| 2 | 75.0 | | |
| 3 | 71.5 | | |
| 4 | 68.0 | | |
| 5 | 72.0 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**10 Static hydrostatic resistance[Sleeve seam]**

**Test Method:** EN ISO 811:2018

**Test principle:**
The hydrostatic head supported by a fabric is a measure of the opposition to the passage of water through the fabric. A specimen is subjected to a steadily increasing pressure of water on one side of the fabric, under standard conditions, until penetration occurs in three places. The pressure at which the water penetrates the fabric at the third place is noted.

**Test equipment:**
Hydrostatic tester
Water, grade 3 water in accordance with ISO 3696.

The environmental conditions of the laboratory and test condition:
Pretreatment: Condition the test specimens at 20.0℃ air at 65.2% RH for 24h
Face side tested
Temperature of the water: 20.0℃
Rate of incereasing water pressure:10cm $H_2O$/min

**Results:**

| Sample | Measured value ($cmH_2O$) | Requirement ($cmH_2O$) | Conclusion |
|---|---|---|---|
| 1 | 72.5 | ≥20<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| 2 | 85.0 | | |
| 3 | 78.0 | | |
| 4 | 75.0 | | |
| 5 | 82.0 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**11 Cleanliness-microorgnism**

**Test Method:** EN ISO 11737-1:2018

**Test principle:**

Take the required samples from the original packaging. Under sterile condition a sample of 100 $cm^2$ was cut and placed in a sterile bottle containing 300 ml of BPW. The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for nonselective aerobic bacteria. Another100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a Sa AGAR plate for total number of yeast and molds. Another100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on blood Agar plate for total number of anaerobic bacteria. Non-selective aerobic bacteria were cultured at 30 ℃ for 3 days and yeast and molds at 25 ℃ for 7 days and anaerobic bacteria at 30℃ for 3 days. The total bioburden is expressed by addition of three culture plates counts. Five parallel samples are tested.

**Test equipment:**

Constant temperature
incubator Electronic balance
Pressure steam sterilizer
Biosafety cabinet
The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture temperature: Bacteria 30℃, Fungi 25℃; Culture time: Bacteria 3 days, Fungi 7 days.

**Results:**

| Sample | total plate count (CFU/100$cm^2$) | Requirement (CFU/100$cm^2$) | Conclusion |
|---|---|---|---|
| 1 | 35 | ≤300<br>(Surgical gown: standard performance)<br>EN 13795-1:2019 | **Pass** |
| 2 | 37 | | |
| 3 | 41 | | |
| 4 | 32 | | |
| 5 | 48 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

12 **The resistance to dry microbial penetration[Material]**

**Test Method:** EN ISO 22612:2005

**Test principle:**
The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

**Test equipment:**
Resistance to dry microbial penetration
test Incubator
Electronic balance
Autoclave

**The environmental conditions of the laboratory and test condition:**
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.
Dimensions of the test specimens:
200mm×200mm Sample: 12 pieces
Vibration frequency: 20800 times/min; Vibration time: 30 min.
Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372
Concentration of bacterium: 1.8 x$10^8$ CFU/g



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TEST REPORT

Number : SHAT06497575
报告号：

Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**The resistance to dry microbial penetration[Material]**

**Results:**

| Sample | Measured value (CFU) | Requirement (CFU) | Conclusion |
|---|---|---|---|
| 1 | 3 | ≤300<br><br>(Surgical gown: standard performance less critical product area)<br><br>EN 13795-1:2019 | Pass |
| 2 | 2 | | |
| 3 | 5 | | |
| 4 | 0 | | |
| 5 | 8 | | |
| 6 | 8 | | |
| 7 | 9 | | |
| 8 | 7 | | |
| 9 | 4 | | |
| 10 | 3 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**13 The resistance to dry microbial penetration[Sleeve seam]**

**Test Method:** EN ISO 22612:2005

**Test principle:**
The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

**Test equipment:**
Resistance to dry microbial penetration
test Incubator
Electronic balance
Autoclave

**The environmental conditions of the laboratory and test condition:**
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.
Dimensions of the test specimens:
200mm×200mm Sample: 12 pieces
Vibration frequency: 20800 times/min; Vibration time: 30 min.
Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372
Concentration of bacterium: 1.8 x$10^8$ CFU/g



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TEST REPORT

Number : SHAT06497575
报告号：

Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**The resistance to dry microbial penetration[Sleeve seam]**

**Results:**

| Sample | Measured value (CFU) | Requirement (CFU) | Conclusion |
|---|---|---|---|
| 1 | 5 | ≤300<br><br>(Surgical gown: standard performance less critical product area)<br><br>EN 13795-1:2019 | Pass |
| 2 | 7 | | |
| 3 | 9 | | |
| 4 | 2 | | |
| 5 | 2 | | |
| 6 | 6 | | |
| 7 | 0 | | |
| 8 | 8 | | |
| 9 | 10 | | |
| 10 | 10 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

14 **The resistance to wet bacterial penetration[Material]**

**Test Method:** EN ISO 22610:2006

**Test principle:**
A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Test equipment:
The resistance to wet bacterial
penetration test Incubator
Electronic balance
Autoclave



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TEST REPORT

Number : SHAT06497575
报告号：

Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**The resistance to wet bacterial penetration[Material]**

**The environmental conditions of the laboratory and test condition:**

Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
Dimensions of the test specimens: 25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 μm
thickness Nutrient agar to from the brim: 3 mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: $2.3x10^4$ CFU/ml

**Results:**

| Sample | Barrier index | Requirement Barrier index | Conclusion |
|---|---|---|---|
| 1 | 4.6 | ≥2.8<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | **Pass** |
| 2 | 4.6 | | |
| 3 | 4.6 | | |
| 4 | 4.5 | | |
| 5 | 4.5 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**15 The resistance to wet bacterial penetration[Sleeve seam]**

**Test Method:** EN ISO 22610:2006

**Test principle:**
A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Test equipment:
The resistance to wet bacterial penetration test Incubator
Electronic balance
Autoclave



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**The resistance to wet bacterial penetration[Sleeve seam]**

**The environmental conditions of the laboratory and test condition:**

Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
Dimensions of the test specimens: 25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 μm
thickness Nutrient agar to from the brim: 3 mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: $2.3x10^4$ CFU/ml

**Results:**

| Sample | Barrier index | Requirement Barrier index | Conclusion |
|---|---|---|---|
| 1 | 4.6 | ≥2.8<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | **Pass** |
| 2 | 4.5 | | |
| 3 | 4.6 | | |
| 4 | 4.5 | | |
| 5 | 4.5 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

16 **Lint and other particles generation in the dry state[Material]**
**Test Method:** EN ISO 9073-10:2004

**Test principle:**
This procedure describes a modified Gelbo Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm.

**Test equipment:**
Gelbo Flex tester with particle counter

**The environmental conditions of the laboratory:**
Test environment temperature: 19.9℃, Relative humidity: 65.3%

**Results:**

| Size of particles counted (μm) | Sample | | Measured value Coefficient of linting $\log_{10}$ | Requirement Coefficient of linting $\log_{10}$ | Conclusion |
|---|---|---|---|---|---|
| 3～25 | A: Face | 1 | 2.8 | ≤4.0<br>(Surgical gown: standard performance critical product area)<br>EN 13795-1:2019 | Pass |
| | | 2 | 2.9 | | |
| | | 3 | 2.8 | | |
| | | 4 | 2.9 | | |
| | | 5 | 2.8 | | |
| | B: Face | 1 | 2.9 | | |
| | | 2 | 2.9 | | |
| | | 3 | 2.9 | | |
| | | 4 | 2.9 | | |
| | | 5 | 3.0 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**17 Lint and other particles generation in the dry state[Sleeve seam]**

**Test Method:** EN ISO 9073-10:2004

**Test principle:**
This procedure describes a modified Gelbo Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm.

Test equipment:
Gelbo Flex tester with particle counter

The environmental conditions of the laboratory:
Test environment temperature: 20.2℃, Relative humidity: 64.8%

**Results:**

| Size of particles counted (μm) | Sample | | Measured value Coefficient of linting $\log_{10}$ | Requirement Coefficient of linting $\log_{10}$ | Conclusion |
|---|---|---|---|---|---|
| 3～25 | A: Face | 1 | 2.8 | ≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019 | Pass |
| | | 2 | 2.9 | | |
| | | 3 | 2.9 | | |
| | | 4 | 2.7 | | |
| | | 5 | 2.8 | | |
| | B: Face | 1 | 2.8 | | |
| | | 2 | 2.9 | | |
| | | 3 | 2.8 | | |
| | | 4 | 2.9 | | |
| | | 5 | 2.9 | | |

Remark :Test was conducted by external provider



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

18 Weight Per Unit Area (ISO 3801-1977):

46.1 g/m²
(1.4 oz/yd²)

**19 胀破强度（干态）[面料]**
**测试方法：** EN ISO 13938-1:1999

**测试原理：**
将试样夹持在可延伸的膜片上，在膜片下面施加液体压力，使膜片和试样发生膨胀。以恒定的速度增加液体体积直至试样破裂，测定胀破强度和胀破扩张度。

测试设备： 胀破试验仪

**实验室环境条件和测试条件：**
预处理条件：温度20.1℃、相对湿度65.3%环境中预处理24h
测试面积：10cm²
**测试结果：**

| 样品 | 实测值 (kPa) | 技术要求 (kPa) | 单项结论 |
|---|---|---|---|
| 1 | 150 | ≥40<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 150 | | |
| 3 | 146 | | |
| 4 | 145 | | |
| 5 | 148 | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**20 胀破强度（干态）[袖缝]**
**测试方法：** EN ISO 13938-1:1999

**测试原理：**
将试样夹持在可延伸的膜片上，在膜片下面施加液体压力，使膜片和试样发生膨胀。以恒定的速度增加液体体积直至试样破裂，测定胀破强度和胀破扩张度。
测试设备： 胀破试验仪

**实验室环境条件和测试条件：**
预处理条件：温度20.1℃、相对湿度65.3%环境中预处理24 h 测试面积：10cm²

**测试结果:**

| 样品 | 实测值 (kPa) | 技术要求 (kPa) | 单项结论 |
|---|---|---|---|
| 1 | 188 | ≥40<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 182 | | |
| 3 | 162 | | |
| 4 | 178 | | |
| 5 | 172 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**21 胀破强度（湿态）[面料]**
**测试方法：** EN ISO 13938-1:1999

**测试原理：**
将试样夹持在可延伸的膜片上，在膜片下面施加液体压力，使膜片和试样发生膨胀。以恒定的速度增加液体体积直至试样破裂，测定胀破强度和胀破扩张度。

测试设备： 胀破试验仪

**实验室环境条件和测试条件：**
测试面积：10cm²

**测试结果：**

| 样品 | 实测值 (kPa) | 技术要求 (kPa) | 单项结论 |
|---|---|---|---|
| 1 | 128 | ≥40<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 158 | | |
| 3 | 134 | | |
| 4 | 142 | | |
| 5 | 146 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**22 胀破强度（湿态）[袖缝]**
**测试方法：** EN ISO 13938-1:1999

**测试原理：**
将试样夹持在可延伸的膜片上，在膜片下面施加液体压力，使膜片和试样发生膨胀。以恒定的速度增加液体体积直至试样破裂，测定胀破强度和胀破扩张度。
**测试设备：** 胀破试验仪

**实验室环境条件和测试条件：**
测试面积：10cm²

**测试结果:**

| 样品 | 实测值 (kPa) | 技术要求 (kPa) | 单项结论 |
|---|---|---|---|
| 1 | 199 | ≥40<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 170 | | |
| 3 | 152 | | |
| 4 | 168 | | |
| 5 | 177 | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**23 断裂强力（干态）[面料]**

**测试方法：** EN 29073-3:1992

**测试原理：**
以恒定伸长速率在试样经纬向拉至断裂，记录的力-伸长曲线确定断裂强度和伸长率的值。

**测试设备：** 拉力测试仪

实验室环境条件和测试条件：
预处理条件：温度20.1℃、相对湿度65.1%环境中预处理
24h 夹距：200mm
速度：100mm/min

测试结果:

| 样品 | 纵向 (N) | 横向 (N) | 技术要求 (N) | 单项结论 |
|---|---|---|---|---|
| 1 | 94.7 | 50.6 | ≥20 (手术衣标准性能关键区域) EN 13795-1:2019 | 符合 |
| 2 | 94.1 | 50.7 | | |
| 3 | 96.8 | 50.8 | | |
| 4 | 97.8 | 48.5 | | |
| 5 | 97.7 | 47.8 | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**24 断裂强力（干态）[袖缝]**

**测试方法：** EN 29073-3:1992

**测试原理：**
以恒定伸长速率在试样经纬向拉至断裂，记录的力-伸长曲线确定断裂强度和伸长率的值。

**测试设备：** 拉力测试仪

实验室环境条件和测试条件：
预处理条件：温度20.1℃、相对湿度65.1%环境中预处理24h
夹距：200mm
速度：100mm/min

**测试结果：**

| 样品 | (N) | | 技术要求 (N) | 单项结论 |
|---|---|---|---|---|
| 1 | 40.3 | | ≥20 (手术衣标准性能关键区域) EN 13795-1:2019 | 符合 |
| 2 | 37.1 | | | |
| 3 | 31.9 | | | |
| 4 | 32.8 | | | |
| 5 | 34.2 | | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**25 断裂强力（湿态）[面料]**

**测试方法：** EN 29073-3:1992

**测试原理：**
以恒定伸长速率在试样经纬向拉至断裂，记录的力-伸长曲线确定断裂强度和伸长率的值。

**测试设备：** 拉力测试仪

**测试条件：**
夹距：
200mm
速度：100mm/min

**测试结果:**

| 样品 | 纵向 (N) | 横向 (N) | 技术要求 (N) | 单项结论 |
|---|---|---|---|---|
| 1 | 95.7 | 45.9 | ≥20 (手术衣标准性能关键区域) EN 13795-1:2019 | 符合 |
| 2 | 97.3 | 46.3 | | |
| 3 | 96.1 | 46.5 | | |
| 4 | 93.0 | 46.9 | | |
| 5 | 96.9 | 50.8 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**26 断裂强力（湿态）[袖缝]**

**测试方法：** EN 29073-3:1992

**测试原理：**
以恒定伸长速率在试样经纬向拉至断裂，记录的力-伸长曲线确定断裂强度和伸长率的值。
**测试设备：** 拉力测试仪

**测试条件：**
夹距：
200mm
速度：100mm/min

**测试结果：**

| 样品 | (N) | | 技术要求 (N) | 单项结论 |
|---|---|---|---|---|
| 1 | 32.7 | | ≥20 (手术衣标准性能关键区域) EN 13795-1:2019 | 符合 |
| 2 | 33.8 | | | |
| 3 | 36.2 | | | |
| 4 | 32.6 | | | |
| 5 | 26.2 | | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**27 静水压[面料]**
**测试方法：** EN ISO 811:2018

**测试原理：**
以织物承受的静水压来表示水透过织物所遇到的阻力。在标准大气条件下，试样的一面承受一个持续上升的水压，直到有三处渗水为止，并记录此时的压力。

**测试设备：** 静水压测试仪
水，符合ISO 3696三级水。
**实验室环境条件和测试条件：**
预处理条件：温度20.0℃、相对湿度65.2%环境中预处理24 h 试样正面接触水
水温：20.0℃
压力速率：10cm $H_2O$ /min

**测试结果：**

| 样品 | 实测值 ($cmH_2O$) | 技术要求 ($cmH_2O$) | 单项结论 |
|---|---|---|---|
| 1 | 67.0 | ≥20<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 75.0 | | |
| 3 | 71.5 | | |
| 4 | 68.0 | | |
| 5 | 72.0 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**28 静水压[袖缝]**
**测试方法：** EN ISO 811:2018

**测试原理：**
以织物承受的静水压来表示水透过织物所遇到的阻力。在标准大气条件下，试样的一面承受一个持续上升的水压，直到有三处渗水为止，并记录此时的压力。

**测试设备：** 静水压测试仪
水，符合ISO 3696三级水。

**实验室环境条件和测试条件：**
预处理条件：温度20.0℃、相对湿度65.2%环境中预处理24 h 试样正面接触水
水温：20.0℃ 压力速率：10cm $H_2O$ /min

**测试结果：**

| 样品 | 实测值 ($cmH_2O$) | 技术要求 ($cmH_2O$) | 单项结论 |
|---|---|---|---|
| 1 | 72.5 | ≥20<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 85.0 | | |
| 3 | 78.0 | | |
| 4 | 75.0 | | |
| 5 | 82.0 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**29 洁净度-微生物**

**测试方法：** EN ISO 11737-1:2018

**测试原理：**

从原始包装中取出所需样品，在无菌条件下剪取一片100cm$^2$样品放到无菌瓶中，加入300ml的缓冲蛋白胨水，在250rpm下振荡时间5min，量取100毫升萃取液，用0.45微米的薄膜过滤后，将滤膜放置到TSA平板上，用于测定非选择性需氧菌；取100毫升萃取液，用0.45微米的薄膜过滤后，将滤膜放置到沙氏琼脂平板上，用于测定酵母菌和霉菌总数；取100毫升萃取液，用0.45微米的薄膜过滤后，将滤膜放置到血琼脂平板上，用于测定厌氧菌总数。非选择性需氧菌在30℃下培养3天，酵母菌和霉菌在25℃培养7天。厌氧菌30℃下培养3天，总的微生物含量用三种培养平板上的计数和来表示。测试5个平行样品。

**测试设备：**

恒温培养箱电子天平
压力蒸汽灭菌锅
生物安全柜

**实验室环境条件和测试条件：**

测试环境温度：24.5℃ 相对湿度：56.0%
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长样品培养温度：细菌30℃，真菌25℃；样品培养时间：细菌3天，真菌7天。

测试结果:

| 样品 | 菌落总数 (CFU/100cm$^2$) | 技术要求 (CFU/100cm$^2$) | 单项结论 |
|---|---|---|---|
| 1 | 35 | ≤300<br>(手术衣标准性能)<br>EN 13795-1:2019 | 符合 |
| 2 | 37 | | |
| 3 | 41 | | |
| 4 | 32 | | |
| 5 | 48 | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**30 阻干态微生物[面料]**
**测试方法：** EN ISO 22612:2005

**测试原理：**
本试验是分别固定在一个容器上的试样进行的，在这些容器中，每个是携带枯草芽孢杆菌滑石粉的容器，1个加入未污染菌的滑石粉的容器作为对照样。在各容器底部离试件下方近距离插入1个培养皿。支撑容器的设备靠1个气体球式振荡器使其振荡，穿透试件的滑石粉全部落到培养皿上，取出培养皿并培养。对生长的菌落进行计数。

**测试设备：**
阻干态微生物穿透测试仪
恒温培养箱
电子天平
压力蒸汽灭菌锅

**实验室环境条件和测试条件：**
测试环境温度：24.5℃, 相对湿度：56.0%
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长培养基名称：TGE琼脂培养基；其他材料：滑石粉和乙醇。
试样尺寸：200mm×200 mm 试样件数：12件
振动频率：20800次/min；振动时间：30min
测试菌种：第四代枯草芽孢杆菌ATCC 9372
细菌浓度 ：1.8 x10 $^{8}$ CFU/g



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TEST REPORT

Number： SHAT06497575
报告号：

Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**阻干态微生物[面料]**
测试结果:

| 样品 | 实测值 (CFU) | 技术要求 (CFU) | 单项结论 |
|---|---|---|---|
| 1 | 3 | ≤300<br>(手术衣标准性能非关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 2 | | |
| 3 | 5 | | |
| 4 | 0 | | |
| 5 | 8 | | |
| 6 | 8 | | |
| 7 | 9 | | |
| 8 | 7 | | |
| 9 | 4 | | |
| 10 | 3 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**31 阻干态微生物[袖缝]**

**测试方法：** EN ISO 22612:2005

**测试原理：**

本试验是分别固定在一个容器上的试样进行的，在这些容器中，每个是携带枯草芽孢杆菌滑石粉的容器，1个加入未污染菌的滑石粉的容器作为对照样。在各容器底部离试件下方近距离插入1个培养皿。支撑容器的设备靠1个气体球式振荡器使其振荡，穿透试件的滑石粉全部落到培养皿上，取出培养皿并培养。对生长的菌落进行计数。

**测试设备：**

阻干态微生物穿透测试仪
恒温培养箱
电子天平
压力蒸汽灭菌锅

**实验室环境条件和测试条件：**

测试环境温度：24.5℃, 相对湿度：56.0%
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长培养基名称：TGE琼脂培养基；其他材料：滑石粉和乙醇。
试样尺寸：200mm×200 mm 试样件数：12件
振动频率：20800次/min；振动时间：30min
测试菌种：第四代枯草芽孢杆菌ATCC 9372
细菌浓度 ：1.8 x10 $^{8}$ CFU/g



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**阻干态微生物[袖缝]**

**测试结果:**

| 样品 | 实测值 (CFU) | 技术要求 (CFU) | 单项结论 |
|---|---|---|---|
| 1 | 5 | ≤300<br>(手术衣标准性能非关键区域)<br>EN 13795-1:2019 | 符合 |
| 2 | 7 | | |
| 3 | 9 | | |
| 4 | 2 | | |
| 5 | 2 | | |
| 6 | 6 | | |
| 7 | 0 | | |
| 8 | 8 | | |
| 9 | 10 | | |
| 10 | 10 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**32 阻湿态微生物[面料]**

**测试方法：** EN ISO 22610:2006

**测试原理：**

将试样放于琼脂培养皿上。一片相同规格的菌片（染菌面向下）放于试件上面，再盖上一片厚约10μm的高密度聚乙烯（HDPE)膜，用两个锥形钢环将三层材料卡在一起，并施加一定的拉伸力。一个耐磨试验指置于材料上面，用于对菌片和试件施加规定的力，使试件与琼脂接触。试验指通过外向轮驱动的旋转杆在15min内以能在整个培养皿表面上移动的方式作用于材料。材料组装的绷紧度靠钢环的自身重量来确定，确保试件在任何一个时间仅有较小的区域与琼脂表面接触。试样进行15min后，更换新的琼脂培养皿，用同一菌片和试件重复进行试验，同一菌片和试件共进行5组试验，每次均操作15min.这样可使试验对总时间内的穿透性进行估测。
最后采用同样的技术估测试件上面的细菌污染情况。为观察细菌菌落，对琼脂培养皿进行培养，然后对菌落数进行计数。结果可以累计的形式来处理，以表征材料的屏障性能和总的时间内的穿透性。

**测试设备：**

阻湿态微生物穿透测试仪
恒温培养箱
电子天平
压力蒸汽灭菌锅

**实验室环境条件和测试条件：**

测试环境温度：24.5℃, 相对湿度：56.0%
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长培养基名称：胰酶大豆琼脂，胰酶大豆肉汤、蛋白胨水、营养琼脂。
试样尺寸：25cm×25cm
载菌材料：30μm厚的溶剂铸制聚氨酯
膜琼脂离平皿口距离：3mm
测试菌种：第五代金黄色葡萄球菌 ATCC 29213
细菌浓度 ：2.3 x10 $^{4}$ CFU/ml



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**阻湿态微生物[面料]**

测试结果:

| 样品 | 屏障指数 | 技术要求<br>屏障指数 | 单项结论 |
|---|---|---|---|
| 1 | 4.6 | ≥2.8<br><br>(手术衣标准性能关键区域)<br><br>EN 13795-1:2019 | 符合 |
| 2 | 4.6 | | |
| 3 | 4.6 | | |
| 4 | 4.5 | | |
| 5 | 4.5 | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**33 阻湿态微生物[袖缝]**

**测试方法：** EN ISO 22610:2006

**测试原理：**

将试样放于琼脂培养皿上。一片相同规格的菌片（染菌面向下）放于试件上面，再盖上一片厚约10μm的高密度聚乙烯（HDPE)膜，用两个锥形钢环将三层材料卡在一起，并施加一定的拉伸力。一个耐磨试验指置于材料上面，用于对菌片和试件施加规定的力，使试件与琼脂接触。试验指通过外向轮驱动的旋转杆在15min内以能在整个培养皿表面上移动的方式作用于材料。材料组装的绷紧度靠钢环的自身重量来确定，确保试件在任何一个时间仅有较小的区域与琼脂表面接触。试样进行15min后，更换新的琼脂培养皿，用同一菌片和试件重复进行试验，同一菌片和试件共进行5组试验，每次均操作15min.这样可使试验对总时间内的穿透性进行估测。
最后采用同样的技术估测试件上面的细菌污染情况。为观察细菌菌落，对琼脂培养皿进行培养，然后对菌落数进行计数。结果可以累计的形式来处理，以表征材料的屏障性能和总的时间内的穿透性。

**测试设备：**

阻湿态微生物穿透测试仪
恒温培养箱
电子天平
压力蒸汽灭菌锅

实验室环境条件和测试条件：
测试环境温度：24.5℃, 相对湿度：56.0%
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长培养基名称：胰酶大豆琼脂，胰酶大豆肉汤、蛋白胨水、营养琼脂。
试样尺寸：25cm×25cm
载菌材料：30μm厚的溶剂铸制聚氨酯
膜琼脂离平皿口距离：3mm
测试菌种：第五代金黄色葡萄球菌ATCC 29213
细菌浓度 ：2.3 x10 $^{4}$ CFU/ml



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TEST REPORT

Number： SHAT06497575
报告号：

Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**阻湿态微生物[袖缝]**

**测试结果:**

| 样品 | 屏障指数 | 技术要求<br>屏障指数 | 单项结论 |
|---|---|---|---|
| 1 | 4.6 | ≥2.8<br><br>(手术衣标准性能关键区域)<br><br>EN 13795-1:2019 | 符合 |
| 2 | 4.5 | | |
| 3 | 4.6 | | |
| 4 | 4.5 | | |
| 5 | 4.5 | | |

备注：此测试是在外部机构进行



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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**34 干态落絮[面料]**

**测试方法：** EN ISO 9073-10:2004

**测试原理：**

改进Gelbo扭曲法，改方法中，样品在试验箱内经受一个扭转和压缩的综合作用，在此扭曲过程中从试验箱中抽出空气，用粒子计数器对空气中的微粒计数并分类，通过计数器的选择，微粒的尺寸范围大概为0.3μm之内或0.5μm至25μm之间。

**测试设备：**

Gelbo扭曲测试仪干态落絮的设备

**实验室环境条件：**

测试环境温度：19.9℃，相对湿度：65.3%

**测试结果：**

| 计数微粒尺寸范围 (μm) | 样品 | | 实测值 落絮系数 $\log_{10}$ | 技术要求 落絮系数 $\log_{10}$ | 单项结论 |
|---|---|---|---|---|---|
| 3～25 | A面 | 1 | 2.8 | ≤4.0<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| | | 2 | 2.9 | | |
| | | 3 | 2.8 | | |
| | | 4 | 2.9 | | |
| | | 5 | 2.8 | | |
| | B面 | 1 | 2.9 | | |
| | | 2 | 2.9 | | |
| | | 3 | 2.9 | | |
| | | 4 | 2.9 | | |
| | | 5 | 3.0 | | |

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Tests Conducted (As Requested By The Applicant)
测试内容（以下测试依据申请人要求进行）

**35 干态落絮[袖缝]**

**测试方法：** EN ISO 9073-10:2004

**测试原理：**

改进Gelbo扭曲法，改方法中，样品在试验箱内经受一个扭转和压缩的综合作用，在此扭曲过程中从试验箱中抽出空气，用粒子计数器对空气中的微粒计数并分类，通过计数器的选择，微粒的尺寸范围大概为0.3μm之内或0.5μm至25μm之间。

**测试设备：**

Gelbo扭曲测试仪干态落絮的设备

**实验室环境条件：**

测试环境温度：20.2℃，相对湿度：64.8%

**测试结果：**

| 计数微粒尺寸范围 (μm) | 样品 | | 实测值 落絮系数 $log_{10}$ | 技术要求 落絮系数 $log_{10}$ | 单项结论 |
|---|---|---|---|---|---|
| 3～25 | A面 | 1 | 2.8 | ≤4.0<br>(手术衣标准性能关键区域)<br>EN 13795-1:2019 | 符合 |
| | | 2 | 2.9 | | |
| | | 3 | 2.9 | | |
| | | 4 | 2.7 | | |
| | | 5 | 2.8 | | |
| | B面 | 1 | 2.8 | | |
| | | 2 | 2.9 | | |
| | | 3 | 2.8 | | |
| | | 4 | 2.9 | | |
| | | 5 | 2.9 | | |

备注：此测试是在外部机构进行



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测试内容（以下测试依据申请人要求进行）

36 织物克重（ISO 3801-1977）：

46.1 克/平方米
（1.4 盎司/平方码）

End of Report

*Remark: The testing data and result issued by this report is just for reference only, not be used as the evidence to the society in the territory of the People's Republic of China.*

*备注：本报告所出具的检测数据及结果仅供参考，在中华人民共和国境内对社会不具有证明作用。*





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