REPORT NUMBER: SHAT06709979

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TEST REPORT

Number : SHAT06709979
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
江苏省苏州市吴江区盛泽镇南三环 1599 号
Attn : Zhang Yanwen
联系人： 张燕文

Date : Nov 20, 2020
日期： 2020 年 11 年 20 日

Sample Description As Declared :
样品描述：

No. Of Sample 样品数量	:	Seventeen 17 件
Fibre Content 成分	:	SMS 无纺布
Sample Name 样品名称	:	SMS Surgical Gown (Irradiation Sterilization) 经过辐照灭菌处理后的SMS 手术衣
Finishing 处理	:	Irradiation Sterilization 辐照灭菌
End Uses 最终用途	:	-
Colour 颜色	:	Blue 蓝色
Style No. 款号	:	TTK-C02

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

Number : SHAT06709979
报告号：

Sterilization (Irradiation) Lot No. 灭菌批号	:	00016236
Sterilization (Irradiation) Date: 灭灭日期		Oct 27, 2020 2020 年 10 月 27 日
Order No./PO No. 订单号	:	-
Buyer's Name 买家名称	:	-
Manufacturer's Name : 供应商名称		Wujiang Tutaike Textile&Finishing Co., Ltd 吴江市涂泰克纺织后整理有限公司
Ref. 参考	:	-

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

Date Sample Received 收件日期	:	Nov 09, 2020 2020 年 11 月 9 日
Date Testing Started 测试开始日期	:	Nov 09, 2020 2020 年 11 月 9 日
Standard 标准	:	EN 13795-1:2019 <Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns> 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 备注	:	The English Version Of This Test Report Is Standard One, The Chinese Version Is Only For Reference 此报告以英文为主，中文仅供参考

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

Jennifer Ren
General Manager

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TEST REPORT

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Conclusion:
结论:

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）[面料]	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

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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]	M
干态落絮[袖缝]	符合
Weight Per Unit Area	#
织物单位面积重量	无结论

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

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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]
胀破强度（干态）**[**面料**]**

Test Method: EN 13795-1:2019/EN ISO 13938-1:1999
测试方法： EN 13795-1:2019/EN ISO 13938-1:1999

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Bursting tester
胀破试验仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Pretreatment: Condition the test specimens at 20.1 ℃ air at 65% RH for 24 h
预处理条件：温度 20.1 ℃、相对湿度 65% 环境中预处理 24h
Test Area: 10cm²
测试面积：10cm²

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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）

Results:
测试结果

Sample 样品	Measured value (kPa) 实测值 (kPa)	Requirement (kPa) 技术要求(kPa)	Conclusion 单项结论
1	103	≥40 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	117		
3	115		
4	108		
5	111		
Median (M_d) 中位值(M_d)	111		
Lower Quartile Value (L_q) 下四分位值(L_q)	108		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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TEST REPORT

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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）

2 Bursting strength（dry state）[Sleeve seam]
胀破强度（干态）**[**袖缝**]**

Test Method: EN 13795-1:2019/EN ISO 13938-1:1999
测试方法： EN 13795-1:2019/EN ISO 13938-1:1999

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Bursting tester
胀破试验仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Pretreatment: Condition the test specimens at 20.1 ℃ air 65.0 % RH for 24 h
预处理条件：温度 20.1 ℃、相对湿度 65.0 %环境中预处理 24h
Test Area: 10cm²
测试面积：10cm

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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）

Result:
测试结果：

Sample 样品	Measured value (kPa) 实测值 (kPa)	Requirement (kPa) 技术要求(kPa)	Conclusion 单项结论
1	166	≥40 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	182		
3	205		
4	201		
5	188		
Median (M_d) 中位值(M_d)	188		
Lower Quartile Value (L_q) 下四分位值(L_q)	182		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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测试内容（以下测试依据申请人要求进行）

3 Bursting strength（wet state）[Material]
胀破强度（湿态）**[**面料**]**

Test Method: EN 13795-1:2019/EN ISO 13938-1:1999
测试方法： EN 13795-1:2019/EN ISO 13938-1:1999

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Bursting tester
胀破试验仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test Area: 10cm²
测试面积：10cm²

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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）

Results:
测试结果

Sample 样品	Measured value (kPa) 实测值 (kPa)	Requirement (kPa) 技术要求(kPa)	Conclusion 单项结论
1	108	≥40 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	108		
3	114		
4	111		
5	109		
Median (M_d) 中位值(M_d)	109		
Lower Quartile Value (L_q) 下四分位值(L_q)	108		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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测试内容（以下测试依据申请人要求进行）

4 Bursting strength（wet state）[Sleeve seam]
胀破强度（湿态）[袖缝]

Test Method: EN 13795-1:2019/EN ISO 13938-1:1999
测试方法： EN 13795-1:2019/EN ISO 13938-1:1999

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Bursting tester
胀破试验仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test Area: 10cm²
测试面积：10cm²

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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）

Results:
测试结果

Sample 样品	Measured value (kPa) 实测值 (kPa)	Requirement (kPa) 技术要求(kPa)	Conclusion 单项结论
1	163	≥40 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	184		
3	193		
4	188		
5	171		
Median (M_d) 中位值(M_d)	184		
Lower Quartile Value (L_q) 下四分位值(L_q)	171		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
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测试内容（以下测试依据申请人要求进行）

5 Breaking strength（dry state）[Material]
断裂强力（干态）[面料]

Test Method: EN 13795-1:2019/EN 29073-3: 1992
测试方法：EN 13795-1:2019/EN 29073-3: 1992
Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Tensile testing machine
拉力测试仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Pretreatment: Condition the test specimens at 20.1℃ air at 65.0% RH for 24 h
预处理条件：温度 20.1℃、相对湿度 65.0%环境中预处理 24h
The distance between the clamps: 200 mm
夹距：200mm
Rate: 100 mm/min
速度：100mm/min

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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）

Results:
测试结果:

Sample 样品	Length (N) 纵向（N）	Width (N) 横向 (N)	Requirement (N) 技术要求(N)	Conclusion 单项结论
1	127.2	71.6	≥20 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	123.3	71.5		
3	131.4	70.4		
4	121.0	69.1		
5	123.9	68.7		
Median (M_d) 中位值(M_d)	123.9	70.4		
Lower Quartile Value (L_q) 下四分位值(L_q)	123.3	69.1		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
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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]
断裂强力（干态）[面料]

Test Method: EN 13795-1:2019/EN 29073-3: 1992
测试方法：EN 13795-1:2019/EN 29073-3: 1992
Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Tensile testing machine
拉力测试仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Pretreatment: Condition the test specimens at 20.1℃ air at 65.0% RH for 24 h
预处理条件：温度 20.1℃、相对湿度 65.0%环境中预处理 24h
The distance between the clamps: 200 mm
夹距：200mm
Rate: 100 mm/min
速度：100mm/min

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TEST REPORT

Number : SHAT06709979
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）

Results:
测试结果:

Sample 样品	（N）	-	Requirement (N) 技术要求(N)	Conclusion 单项结论
1	111.5	-	≥20 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	109.0	-		
3	107.0	-		
4	110.2	-		
5	106.4	-		
Median (M_d) 中位值(M_d)	109.0	-		
Lower Quartile Value (L_q) 下四分位值 (L_q)	107.0	-		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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测试内容（以下测试依据申请人要求进行）

7 Breaking strength（wet state）[Material]
断裂强力（湿态）[面料]

Test Method: EN 13795-1:2019/EN 29073-3: 1992
测试方法：EN 13795-1:2019/EN 29073-3: 1992
Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Tensile testing machine
拉力测试仪

Test condition:
测试条件：
The distance between the clamps: 200 mm
夹距：200mm
Rate: 100 mm/min
速度：100mm/min

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测试内容（以下测试依据申请人要求进行）

Results:
测试结果:

Sample 样品	Length (N) 纵向（N）	Width (N) 横向 (N)	Requirement (N) 技术要求(N)	Conclusion 单项结论
1	119.4	74.3	≥20 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	117.8	68.6		
3	118.7	73.3		
4	123.0	69.4		
5	119.0	75.3		
Median (M_d) 中位值 (M_d)	119.0	73.3		
Lower Quartile Value (L_q) 下四分位值(L_q)	118.7	69.4		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
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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]
断裂强力（湿态）[袖缝]

Test Method: EN 13795-1:2019/EN 29073-3: 1992
测试方法：EN 13795-1:2019/EN 29073-3: 1992

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Tensile testing machine
拉力测试仪

Test condition:
测试条件：
The distance between the clamps: 200 mm
夹距：200mm
Rate: 100 mm/min
速度：100mm/min

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Results:
测试结果:

Sample 样品	（N）	-	Requirement (N) 技术要求(N)	Conclusion 单项结论
1	111.3	-	≥20 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	120.0	-		
3	114.4	-		
4	114.9	-		
5	106.5	-		
Median (M_d) 中位值(M_d)	114.4	-		
Lower Quartile Value (L_q) 下四分位值(L_q)	111.3	-		

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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）

9 Static hydrostatic resistance[Material]
静水压[面料]

Test Method: EN 13795-1:2019/EN ISO 811: 2018
测试方法: EN 13795-1:2019/EN ISO 811: 2018

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Hydrostatic tester
静水压测试仪
Water, grade 3 water in accordance with ISO 3696.
水，符合 ISO 3696 三级水。

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Pretreatment: Condition the test specimens at 20.1℃ air at 65.1% RH for 24 h
预处理条件：温度 20.1 ℃、相对湿度 65.1 %环境中预处理 24h
Face side tested
试样正面接触水
Temperature of the water: 20.0℃
水温：20.0℃
Rate of incereasing water pressure:10cm H_2O/min
压力速率：10cm H_2O/min

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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）

Results:
测试结果:

Sample 样品	Measured value(cmH_2O) 实测值(cmH_2O)	技术要求(cmH_2O) Requirement(cmH_2O)	Conclusion 单项结论
1	> 200	≥20 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	> 200		
3	> 200		
4	> 200		
5	> 200		
Median (M_d) 中位值(M_d)	> 200		
Lower Quartile Value (L_q) 下四分位值(L_q)	> 200		

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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]
静水压[袖缝]

Test Method: EN 13795-1:2019/EN ISO 811: 2018
测试方法: EN 13795-1:2019/EN ISO 811: 2018

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Hydrostatic tester
静水压测试仪
Water, grade 3 water in accordance with ISO 3696.
水，符合 ISO 3696 三级水。

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Pretreatment: Condition the test specimens at 20.1 ℃ air at 65.1 % RH for 24 h
预处理条件：温度 20.1 ℃、相对湿度 65.1 %环境中预处理 24h
Face side tested
试样正面接触水
Temperature of the water: 20.0℃
水温：20.0℃
Rate of incereasing water pressure:10cm H_2O/min
压力速率：10cm H_2O/min

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测试内容（以下测试依据申请人要求进行）

Results:
测试结果:

Sample 样品	Measured value(cmH_2O) 实测值(cmH_2O)	技术要求(cmH_2O) Requirement(cmH_2O)	Conclusion 单项结论
1	> 200	≥20 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	> 200		
3	> 200		
4	> 200		
5	> 200		
Median (M_d) 中位值(M_d)	> 200		
Lower Quartile Value (L_q) 下四分位值(L_q)	> 200		

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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
洁净度-微生物

Test Method: EN 13795-1:2019/EN ISO 11737-1: 2018
测试方法：EN 13795-1:2019/EN ISO 11737-1: 2018

Test principle:
测试原理：
Take the required samples from the original packaging. Under sterile condition a sample of 100 cm 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.
从原始包装中取出所需样品，在无菌条件下剪取一片 100cm 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。

Test equipment:
测试设备：
Constant temperature incubator
恒温培养箱
Electronic balance
电子天平
Pressure steam sterilizer
压力蒸汽灭菌锅
Biosafety cabinet
生物安全柜

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The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test environment temperature: 24.5℃, Relative humidity: 56.0%
测试环境温度：24.5℃ 相对湿度：56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
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
Culture temperature: Bacteria 30℃, Fungi 25℃; Culture time: Bacteria 3 days, Fungi 7 days.
培养温度：细菌 30℃，真菌 25℃；样品培养时间：细菌 3 天，真菌 7 天。

Results:
测试结果:

Sample 样品	total plate count (CFU/100cm²) 菌落总数 (CFU/100cm²)	Requirement (CFU/100cm²) 技术要求(CFU/100cm²)	Conclusion 单项结论
1	0	≤300 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
2	0		
3	0		
4	0		
5	0		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
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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]
阻干态微生物[面料]

Test Method: EN 13795-1:2019/EN ISO 22612: 2005
测试方法：EN 13795-1:2019/EN ISO 22612: 2005

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Resistance to dry microbial penetration test
阻干态微生物穿透测试仪
Incubator
恒温培养箱
Electronic balance
电子天平
Autoclave
压力蒸汽灭菌锅

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The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test environment temperature: 22.0℃, Relative humidity: 65.0%
测试环境温度：22.0℃, 相对湿度：65.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
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
Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.
培养基名称：TGE 琼脂培养基；其他材料：滑石粉和乙醇。
Dimensions of the test specimens: 200mm×200mm
试样尺寸：200mm×200mm
Sample: 12 pieces
试样件数：12 件
Vibration frequency: 20800 times/min; Vibration time: 30 min.
振动频率：20800 次/min；振动时间：30min。
Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372
测试菌种：第四代枯草芽孢杆菌 ATCC 9372
Concentration of bacterium: 2.0 x10^8 CFU/g
菌液浓度：2.0 x10^8 CFU/g
Test Side: Outer Part
测试面：外层

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TEST REPORT

Number : SHAT06709979
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）

Results:
测试结果：

Sample 样品	Measured value (CFU) 实测值(CFU)	Requirement (CFU) 技术要求(CFU)	Conclusion 单项结论
1	0	≤300 (Surgical gown: standard performance less critical product area) (手术衣标准性能非关键区域) EN 13795-1:2019	Pass 符合
2	0		
3	0		
4	0		
5	0		
6	0		
7	0		
8	0		
9	0		
10	0		
Median(M_d) 中位值(M_d)	0		
Upper Quartile (U_q) 上四分位值(U_q)	0		

Remark: CFU = Colony Forming Units
备注：CFU = 菌落形成单位

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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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]
阻干态微生物[袖缝]

Test Method: EN 13795-1:2019/EN ISO 22612: 2005
测试方法：EN 13795-1:2019/EN ISO 22612: 2005

Test principle:
测试原理：
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.
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。

Test equipment:
测试设备：
Resistance to dry microbial penetration test
阻干态微生物穿透测试仪
Incubator
恒温培养箱
Electronic balance
电子天平
Autoclave
压力蒸汽灭菌锅

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测试内容（以下测试依据申请人要求进行）

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test environment temperature: 22.0℃, Relative humidity: 65.0%
测试环境温度：22.0℃, 相对湿度：65.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
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
Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.
培养基名称：TGE 琼脂培养基；其他材料：滑石粉和乙醇。
Dimensions of the test specimens: 200mm×200mm
试样尺寸：200mm×200mm
Sample: 12 pieces
试样件数：12 件
Vibration frequency: 20800 times/min; Vibration time: 30 min.
振动频率：20800 次/min；振动时间：30min。
Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372
测试菌种：第四代枯草芽孢杆菌 ATCC 9372
Concentration of bacterium: 2.0 x10^8 CFU/g
菌液浓度：2.0 x10^8 CFU/g
Test Side: Outer Part
测试面：外层

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测试内容（以下测试依据申请人要求进行）

Results:
测试结果：

Sample 样品	Measured value (CFU) 实测值(CFU)	Requirement (CFU) 技术要求(CFU)	Conclusion 单项结论
1	0	≤300 (Surgical gown: standard performance less critical product area) (手术衣标准性能非关键区域) EN 13795-1:2019	Pass 符合
2	0		
3	0		
4	0		
5	0		
6	0		
7	0		
8	0		
9	0		
10	0		
Median(M_d) 中位值(M_d)	0		
Upper Quartile (U_q) 上四分位值(U_q)	0		

Remark: CFU = Colony Forming Units
备注：CFU = 菌落形成单位

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
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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]
阻湿态微生物[面料]

Test Method: EN 13795-1:2019/EN ISO 22610: 2006
测试方法：EN 13795-1:2019/EN ISO 22610: 2006

Test principle:
测试原理：
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.
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 10µ m 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。

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测试内容（以下测试依据申请人要求进行）

Test equipment:
测试设备：
The resistance to wet bacterial penetration test
阻湿态微生物穿透测试仪
Incubator
恒温培养箱
Electronic balance
电子天平
Autoclave
压力蒸汽灭菌锅

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test environment temperature: 24.5℃, Relative humidity: 56.0%
测试环境温度：24.5℃, 相对湿度：56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
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
Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
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。
Dimensions of the test specimens: 25cm×25cm
试样尺寸：25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 μm
载菌材料：30μm 厚的溶剂铸制聚氨酯膜
thickness Nutrient agar to from the brim: 3 mm
琼脂离平皿口距离：3mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
测试菌种：第五代金黄色葡萄球菌 ATCC 29213
Concentration of bacterium: 2.2 x 10^4 CFU/ml
菌液浓度：2.2x10^4 CFU/ml
Number of samples: 5
样品数量：5
Test Side: Outer part
测试面：外层

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测试内容（以下测试依据申请人要求进行）

Results:
测试结果：

	Colony Counts (CFU) 菌落数 (CFU)						
	Plate 1 （X1） 平皿 1 （X1）	Plate 2 （X2） 平皿 2 （X2）	Plate 3 （X3） 平皿 3 （X3）	Plate 4 （X4） 平皿 4 （X4）	Plate 5 （X5） 平皿 5 （X5）	Plate 6 (Z) 平皿 6 (Z)	
Interval (min) 间隔时（min）	0-15	15-30	30-45	45-60	60-75	---	I_B
1	0	0	0	0	0	455	6.0
2	0	0	0	0	0	377	6.0
3	0	0	0	0	0	379	6.0
4	0	0	0	0	0	411	6.0
5	0	0	0	0	0	420	6.0
Requirement I_B 标准值 I_B	≥2.8 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019						
Conclusion 单项结论	Pass 符合						

Remark: CFU = Colony Forming Units
I_B = Barrier Index
备注： CFU= 菌落形成单位
I_B =屏蔽指数

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备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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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]
阻湿态微生物[袖缝]

Test Method: EN 13795-1:2019/EN ISO 22610: 2006
测试方法：EN 13795-1:2019/EN ISO 22610: 2006

Test principle:
测试原理：
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.
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 10µ m 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。

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测试内容（以下测试依据申请人要求进行）

Test equipment:
测试设备：
The resistance to wet bacterial penetration test
阻湿态微生物穿透测试仪
Incubator
恒温培养箱
Electronic balance
电子天平
Autoclave
压力蒸汽灭菌锅

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Test environment temperature: 24.5℃, Relative humidity: 56.0%
测试环境温度：24.5℃, 相对湿度：56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
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
Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
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。
Dimensions of the test specimens: 25cm×25cm
试样尺寸：25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 μm
载菌材料：30μm 厚的溶剂铸制聚氨酯膜
thickness Nutrient agar to from the brim: 3 mm
琼脂离平皿口距离：3mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
测试菌种：第五代金黄色葡萄球菌 ATCC 29213
Concentration of bacterium: 2.2 x 10^4 CFU/ml
菌液浓度：2.2x10^4 CFU/ml
Number of samples: 5
样品数量：5
Test Side: Outer part
测试面：外层

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测试内容（以下测试依据申请人要求进行）

Results:
测试结果：

	Colony Counts (CFU) 菌落数 (CFU)						
	Plate 1 （X1） 平皿 1 （X1）	Plate 2 （X2） 平皿 2 （X2）	Plate 3 （X3） 平皿 3 （X3）	Plate 4 （X4） 平皿 4 （X4）	Plate 5 （X5） 平皿 5 （X5）	Plate 6 (Z) 平皿 6(Z)	
Interval (min) 间隔时（min）	0-15	15-30	30-45	45-60	60-75	---	I_B
1	0	0	0	0	0	388	6.0
2	0	0	0	0	0	443	6.0
3	0	0	0	0	0	449	6.0
4	0	0	0	0	0	377	6.0
5	0	0	0	0	0	362	6.0
Requirement I_B 标准值 I_B	≥2.8 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019						
Conclusion 单项结论	Pass 符合						

Remark: CFU = Colony Forming Units
I_B = Barrier Index
备注： CFU= 菌落形成单位
I_B =屏蔽指数

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
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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]
干态落絮[面料]

Test Method: EN 13795-1:2019/EN ISO 9073-10: 2004
测试方法：EN 13795-1:2019/EN ISO 9073-10: 2004

Test principle:
测试原理：
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.
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 0.3μ m 之内或 0.5μ m 至 25μ m 之间。

Test equipment:
测试设备：
Gelbo Flex tester with particle counter
Gelbo 扭曲测试仪干态落絮的设备

The environmental conditions of the laboratory:
实验室环境条件：
Test environment temperature: 20.1℃, Relative humidity: 64.9%
测试环境温度：20.1 ℃，相对湿度：64.9%

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TEST REPORT

Number： SHAT06709979
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）

Results:
测试结果

Size of particles counted (μm) 计数微粒尺寸范围 (μm)	Sample 样品		Measured value Coefficient of linting log_{10} 实测值落絮系数 log_{10}	Requirement Coefficient of linting log_{10} 技术要求落絮系数 log_{10}	Conclusion 单项结论
3～25	A: Face A 面	1	2.7	≤4.0 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
		2	2.7		
		3	2.7		
		4	2.7		
		5	2.7		
		Median(M_d) 中位值(M_d)	2.7		
		Upper Quartile(U_q) 上四分位值 (U_q)	2.7		
	B: Face B 面	1	2.5		
		2	2.5		
		3	2.6		
		4	2.5		
		5	2.5		
		Median(M_d) 中位值(M_d)	2.5		
		Upper Quartile(U_q) 上四分位值 (U_q)	2.5		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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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]
干态落絮[袖缝]

Test Method: EN 13795-1:2019/EN ISO 9073-10: 2004
测试方法：EN 13795-1:2019/EN ISO 9073-10: 2004

Test principle:
测试原理：
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.
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 0.3μ m 之内或 0.5μ m 至 25μ m 之间。

Test equipment:
测试设备：
Gelbo Flex tester with particle counter
Gelbo 扭曲测试仪干态落絮的设备

The environmental conditions of the laboratory:
实验室环境条件：
Test environment temperature: 20.1℃, Relative humidity: 64.9 %
测试环境温度：20.1 ℃，相对湿度：64.9 %

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Results:
测试结果

Size of particles counted (μm) 计数微粒尺寸范围 (μm)	Sample 样品		Measured value Coefficient of linting log_{10} 实测值落絮系数 log_{10}	Requirement Coefficient of linting log_{10} 技术要求落絮系数 log_{10}	Conclusion 单项结论
3～25	A: Face A 面	1	2.4	≤4.0 (Surgical gown: standard performance critical product area) (手术衣标准性能关键区域) EN 13795-1:2019	Pass 符合
		2	2.4		
		3	2.4		
		4	2.4		
		5	2.4		
		Median(M_d) 中位值(M_d)	2.4		
		Upper Quartile(U_q) 上四分位值 (U_q)	2.4		
	B: Face B 面	1	2.7		
		2	2.6		
		3	2.5		
		4	2.6		
		5	2.6		
		Median(M_d) 中位值(M_d)	2.6		
		Upper Quartile(U_q) 上四分位值 (U_q)	2.6		

Remark: *Test Item Is Accredited And Subcontracted To The Organization Complied With ISO/IEC 17025.
备注： *测试项目为已认可的分包项目，符合 ISO/IEC 17025 的要求。

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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):
织物单位面积重量 (ISO 3801-1977):

67.1 g/m²
67.1 克/平方米
(2.0 oz/yd²)
(2.0 盎司/平方码)

End of Report

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