REPORT NUMBER: SHAT06523847

TEST REPORT

Number : SHAT06523847

Applicant : KUNSHAN JIEHONG NONWOVEN PRODUCT CO.,LTD.
NO.895 XINLE ROAD, DIANSHANHU TOWN
KUNSHAN CITY, JIANGSU PROVINCE
Attn : YUXIANGHONG

Date : Jun 23, 2020

Sample Description As Declared :

No. Of Sample	:	Eighteen
Fibre Content	:	Breathable Film + PP
Sample Name	:	Surgical Gown
Finishing	:	-
End Uses	:	-
Colour	:	Blue
Style No.	:	XL
Order No./PO No.	:	-
Buyer's Name	:	-
Manufacturer's Name	:	Kunshan Jiehong Nonwoven Product Co., Ltd.
Standard	:	EN 13795-1:2019 <Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns>
Ref.	:	-

Applicant's Provided Care Instruction/Label : -

Date Sample Received : Jun 04, 2020
Date Testing Started : Jun 08, 2020

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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Conclusion:

Bursting strength(dry state)[Material]	M
Bursting strength(dry state)[Sleeve seam]	M
Bursting strength(wet state)[Material]	M
Bursting strength(wet state)[Sleeve seam]	M
Breaking strength(dry state)[Material]	M
Breaking strength(dry state)[Sleeve seam]	M
Breaking strength(wet state)[Material]	M
Breaking strength(wet state)[Sleeve seam]	M
Static hydrostatic resistance[Material]	M
Static hydrostatic resistance[Sleeve seam]	M
Cleanliness-microorgnism	M
The resistance to dry microbial penetration[Material]	M
The resistance to dry microbial penetration[Sleeve seam]	M
The resistance to wet bacterial penetration[Material]	M
The resistance to wet bacterial penetration[Sleeve seam]	M
Lint and other particles generation in the dry state[Material]	M
Lint and other particles generation in the dry state[Sleeve seam]	M
Weight Per Unit Area	#

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "#"-No comment

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TEST REPORT

Number： SHAT06523847

Tests Conducted (As Requested By The Applicant)

1 Bursting strength（dry state）[Material]
Test Method: EN 13795-1:2019 / 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 65.0% RH for 24 h
Test Area: 10cm²

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	85.0	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	79.0		
3	52.7		
4	73.9		
5	81.4		

Remark : This test was conducted by external provider.

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TEST REPORT

Number： SHAT06523847

Tests Conducted (As Requested By The Applicant)

2 Bursting strength（dry state）[Sleeve seam]
Test Method: EN 13795-1:2019 / 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 65.0% RH for 24 h
Test Area: 10cm²

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	152	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	140		
3	172		
4	157		
5	166		

Remark : This test was conducted by external provider.

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Tests Conducted (As Requested By The Applicant)

3 Bursting strength（wet state）[Material]
Test Method: EN 13795-1:2019 / 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

Result:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	99.4	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	85.0		
3	81.4		
4	83.8		
5	95.4		

Remark：This test was conducted by external provider.

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TEST REPORT

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Tests Conducted (As Requested By The Applicant)

4 Bursting strength（wet state）[Sleeve seam]
Test Method: EN 13795-1:2019 / 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	172	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	152		
3	156		
4	161		
5	159		

Remark : This test was conducted by external provider.

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TEST REPORT

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Tests Conducted (As Requested By The Applicant)

5 Breaking strength（dry state）[Material]
Test Method: EN 13795-1:2019 / 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 65.0% 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	52.4	29.3	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	55.1	28.5		
3	55.5	27.6		
4	51.0	28.2		
5	52.2	29.2		

Remark：This test was conducted by external provider.

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Number： SHAT06523847

Tests Conducted (As Requested By The Applicant)

6 Breaking strength（dry state）[Sleeve seam]
Test Method: EN 13795-1:2019 / 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 65.0% RH for 24 h
The Distance between the clamps: 200 mm
Rate: 100 mm/min

Results:

Sample	(N)		Requirement (N)	Conclusion
1	35.7		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	39.3			
3	23.0			
4	26.6			
5	38.9			

Remark：This test was conducted by external provider.

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Tests Conducted (As Requested By The Applicant)

7 Breaking strength（wet state）[Material]
Test Method: EN 13795-1:2019 / 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	55.8	25.3	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	58.8	28.4		
3	56.8	27.3		
4	42.4	28.6		
5	49.0	27.7		

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TEST REPORT

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Tests Conducted (As Requested By The Applicant)

8 Breaking strength（wet state）[Sleeve seam]

Test Method: EN 13795-1:2019 / 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	40.7		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	37.0			
3	32.5			
4	35.8			
5	34.7			

Remark : This test was conducted by external provider.

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TEST REPORT

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Tests Conducted (As Requested By The Applicant)

9 Static hydrostatic resistance[Material]

Test Method: EN 13795-1:2019 / 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 20.1℃airat 64.7%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	72.0	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	77.5		
3	84.0		
4	80.5		
5	75.0		

Remark : This test was conducted by external provider.

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TEST REPORT

Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

10 Static hydrostatic resistance[Sleeve seam]
Test Method: EN 13795-1:2019 / 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 20.1℃ air at 64.7% 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	123	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	107		
3	114		
4	117		
5	105		

Remark : This test was conducted by external provider.

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Tests Conducted (As Requested By The Applicant)

11 Cleanliness-microorgnism

Test Method: EN 13795-1:2019 / 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/100cm^2)	Requirement (CFU/100cm^2)	Conclusion
1	31	≤300 (Surgical gown: standard performance) EN 13795-1:2019	Pass
2	34		
3	41		
4	34		
5	41		

Remark : This test was conducted by external provider.

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TEST REPORT

Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

12 The resistance to dry microbial penetration[Material]
Test Method: EN 13795-1:2019 / 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: 1.9 x10^8 CFU/g

Result:

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

Remark : This test was conducted by external provider.

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TEST REPORT

Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

13 The resistance to dry microbial penetration[Sleeve seam]
Test Method: EN 13795-1:2019 / 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 acontrol. 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: 1.9 x10^8 CFU/g

Result:

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

Remark : This test was conducted by external provider.

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TEST REPORT

Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

14 The resistance to wet bacterial penetration[Material]

Test Method: EN 13795-1:2019 / 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

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: $2.5x10^4$ CFU/ml

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Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

Results (CONT'D)

Result:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	6.0	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	6.0		
3	6.0		
4	6.0		
5	6.0		

Remark : This test was conducted by external provider.

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Tests Conducted (As Requested By The Applicant)

15 The resistance to wet bacterial penetration[Sleeve seam]
Test Method: EN 13795-1:2019 / 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

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: $2.5x10^4$ CFU/ml

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Tests Conducted (As Requested By The Applicant)

Results (CONT'D)

Result:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	6.0	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	**Pass**
2	6.0		
3	6.0		
4	6.0		
5	6.0		

Remark : This test was conducted by external provider.

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TEST REPORT

Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

16 Lint and other particles generation in the dry state[Material]
Test Method: EN 13795-1:2019 / 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: 20.0℃, Relative humidity: 65.1%

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	1.5	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	1.5		
		3	1.9		
		4	2.0		
		5	1.4		
	B: Face	1	1.8		
		2	1.4		
		3	1.6		
		4	1.5		
		5	2.0		

Remark : This test was conducted by external provider.

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TEST REPORT

Number： SHAT06523847

Tests Conducted (As Requested By The Applicant)

17 Lint and other particles generation in the dry state[Sleeve seam]
Test Method: EN 13795-1:2019 / 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: 20.0℃, Relative humidity: 65.0%

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	1.9	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	1.4		
		3	1.8		
		4	1.9		
		5	1.5		
	B: Face	1	2.2		
		2	1.3		
		3	2.0		
		4	2.2		
		5	1.5		

Remark : This test was conducted by external provider.

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TEST REPORT

Number : SHAT06523847

Tests Conducted (As Requested By The Applicant)

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

Weight	44.6 g/m² (1.3 oz/yd²)

End of Report

Remark: This statement of conformity is only based on the actual measured test result by the laboratory, without taking the influence of uncertainty into accord.

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