

# Test Report

(Electronic version)

Verification Code: FGEE-1611-04  
Verification Website: www.gtgc.net.cn

No: 21R000957

Issue Date: 2021-03-31

Applicant: WUJIANG TUTAIKE TEXTILES & FINISHING CO.,LTD  
Address: NO.1599,3RD SOUTHERN RING ROAD, SHENGZE TOWN, WUJIANG, JIANGSU, 215200,  
CHINA

Information confirmed by applicant:

Surgical gown

Quantity: 20 pieces

Sterilization model : Irradiatio Sterilization

Lot/Batch : TTK-20200820

Manufacture's name: WUJIANG TUTAIKE TEXTILES & FINISHING CO.,LTD

Standard Adopted:

EN 13795-1:2019 <Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns>

Date Received/Date Test Started: 2021-03-22

Conclusion:

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
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
Static hydrostatic resistance[Material]	M
Static hydrostatic resistance[Sleeve seam]	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

Approved By:

WanLi Hu Engineer

WanLi Hu



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

M

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

Remark:

All the tested items are tested under the standard condition (except for indication).

Copies of the report are valid only re-stamped.

The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By:

WanLi Hu Engineer

*WanLi Hu*



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# Test Report

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## 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:

Testing and conditioning environment: Temperature: 20.1°C, relative humidity: 65.1%

The distance between the clamps: 200mm

Rate: 100 mm/min

### Results:

Sample	MD (N)	CD (N)	Requirement (N)	Conclusion
1	76.8	43.0	≥20	Pass
2	70.5	43.1	(Surgical gown: standard performance critical product area)	
3	80.0	45.4	EN 13795-1:2019	
4	78.2	46.8		
5	82.5	43.0		



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# Test Report

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**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:**

Testing and conditioning environment: Temperature: 20.1℃, relative humidity: 65.1%

The distance between the clamps: 200mm

Rate: 100 mm/min

**Results:**

Sample	(N)	Requirement (N)	Conclusion
1	41.7	≥20	Pass
2	39.0	(Surgical gown: standard performance critical product area)	
3	41.5	EN 13795-1:2019	
4	41.6		
5	42.0		



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# Test Report

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No: 21R000957

**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: 200mm

Rate: 100 mm/min

**Results:**

Sample	MD (N)	CD (N)	Requirement (N)	Conclusion
1	73.8	42.5	≥20	Pass
2	70.2	46.8	(Surgical gown: standard performance critical product area) EN 13795-1:2019	
3	76.2	45.8		
4	75.6	40.4		
5	77.5	44.1		



# Test Report

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No: 21R000957

**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: 200mm

Rate: 100 mm/min

**Results:**

Sample	(N)	Requirement (N)	Conclusion
1	40.8	≥20  (Surgical gown: standard performance critical product area)  EN 13795-1:2019	Pass
2	40.6		
3	41.8		
4	41.8		
5	39.6		



# Test Report

(Electronic version)

No: 21R000957

**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:**

Testing and conditioning environment: Temperature: 20.1℃, relative humidity: 65.1%

Test area: 10cm<sup>2</sup>

**Results:**

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	123	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	82.6		
3	70.6		
4	88.9		
5	99.5		





# Test Report

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## 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:

Testing and conditioning environment: Temperature: 20.1℃, relative humidity: 65.1%

Test area: 10cm<sup>2</sup>

### Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	275	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	281		
3	278		
4	258		
5	260		



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# Test Report

(Electronic version)

No: 21R000957

## 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: 10cm<sup>2</sup>

### Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	46.7	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	56.3		
3	70.6		
4	69.5		
5	65.0		



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# Test Report

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## 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: 10cm<sup>2</sup>

### Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	275	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	241		
3	267		
4	257		
5	260		



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# Test Report

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## 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:

Testing and conditioning environment: Temperature: 20.1°C, relative humidity: 65.1%

Face side tested

Temperature of the water: 20.0°C

Rate of increasing water pressure: 10cmH<sub>2</sub> O/min

### Results:

Sample	Measured value (cmH <sub>2</sub> O)	Requirement (cmH <sub>2</sub> O)	Conclusion
1	59.0	≥20  (Surgical gown: standard performance critical product area)  EN 13795-1:2019	<b>Pass</b>
2	95.5		
3	74.0		
4	84.5		
5	80.0		



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# Test Report

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No: 21R000957

## 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:

Testing and conditioning environment: Temperature: 20.1°C, relative humidity: 65.1%

Face side tested

Temperature of the water: 20.0°C

Rate of increasing water pressure: 10cmH<sub>2</sub> O/min

### Results:

Sample	Measured value (cmH <sub>2</sub> O)	Requirement (cmH <sub>2</sub> O)	Conclusion
1	53.5	≥20  (Surgical gown: standard performance critical product area)  EN 13795-1:2019	Pass
2	47.5		
3	66.0		
4	59.5		
5	55.0		



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# Test Report

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No: 21R000957

## 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: 22.0°C, Relative humidity: 65.0%  
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:  $2.0 \times 10^8$  CFU/g

### Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	3	$\leq 300$  (Surgical gown: standard performance less critical product area)  EN 13795-1:2009	Pass
2	3		
3	1		
4	2		
5	6		
6	2		
7	2		
8	4		
9	4		
10	3		



# Test Report

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No: 21R000957

## 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: 22.0°C, Relative humidity: 65.0%  
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:  $2.0 \times 10^8$  CFU/g

### Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	2	$\leq 300$  (Surgical gown: standard performance less critical product area)  EN 13795-1:2009	Pass
2	5		
3	5		
4	7		
5	3		
6	2		
7	6		
8	1		
9	1		
10	5		



# Test Report

(Electronic version)

No: 21R000957

## 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

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

Test environment temperature: 24.5°C, 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:  $2.0 \times 10^4$  CFU/ml



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**Results:**

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.2	$\geq 2.8$ (Surgical gown: standard performance critical product area) EN 13795-1:2019	<b>Pass</b>
2	4.3		
3	4.2		
4	4.2		
5	4.2		



# Test Report

(Electronic version)

No: 21R000957

## 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

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

Test environment temperature: 24.5°C, 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:  $2.0 \times 10^4$  CFU/ml



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# Test Report

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No: 21R000957

Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.2	≥2.8  (Surgical gown: standard performance critical product area)  EN 13795-1:2019	Pass
2	4.1		
3	4.2		
4	4.2		
5	4.2		



# Test Report

(Electronic version)

No: 21R000957

**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: 20.1°C, Relative humidity: 65.1%

**Results:**

Size of particles counted (μm)	Sample	Measured value Coefficient of linting log <sub>10</sub>	Requirement Coefficient of linting log <sub>10</sub>	Conclusion	
3~25	A: Face	1	3.2	≤4.0  (Surgical gown: standard performance critical product area)  EN 13795-1:2019	<b>Pass</b>
		2	3.2		
		3	3.2		
		4	3.2		
		5	3.1		
	B: Face	1	3.0		
		2	2.9		
		3	2.9		
		4	3.1		
		5	2.9		



# Test Report

(Electronic version)

No: 21R000957

## 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: 20.1°C, Relative humidity: 65.2%

### Results:

Size of particles counted (μm)	Sample	Measured value Coefficient of linting log <sub>10</sub>	Requirement Coefficient of linting log <sub>10</sub>	Conclusion	
3~25	A: Face	1	2.9	≤4.0  (Surgical gown: standard performance critical product area)  EN 13795-1:2019	Pass
		2	3.3		
		3	3.2		
		4	3.2		
		5	3.1		
	B: Face	1	3.2		
		2	3.2		
		3	3.1		
		4	3.2		
		5	3.2		



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—End of Report—