Test Report

Verification Code: NCNY-2948-44
Verification Website: www.gttc.net.cn

No:21R002065MO Issue Date: 2022-02-10

Applicant: Isol8 Healthcare Ltd
Address: Unit 1 Westside, Monavalley Business Park, Tralee, CO. Kerry, Ireland, V92 K258

Information confirmed by applicant:

Nonwoven Standard Surgical Gown (SMS)

Quantity: 16 pieces

Model: ISOL/8 Elemental (MPC: IS8E01-IS8E07)

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: 2021-08-12

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
Cleanliness-microorganism	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

Wan Li Hu

Digitally signed by Granaci Boris
Date: 2023.05.05 12:58:09 EEST
Reason: MoldSign Signature
Location: Moldova

广州检验检测认证集团有限公司 检验检测专用章 (GPZ)

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电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

Verification Code: NCNY-2948-44
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No:21R002065MO Issue Date: 2022-02-10

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:
This report replaces test report 21R002065 which has become invalid automatically.
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: Wan Li Hu

WanLi Hu Engineer

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Test Report

No: 21R002065MO

广州广检检验检测认证集团有限公司 检验检测专用章 (GF2)

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电话：020-37721161/66348638

Test Report

No: 21R002065MO

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℃，relative humidity: 65.1%
The distance between the clamps: 200mm
Rate: 100 mm/min

Results:

Sample	MD (N)	CD (N)	Requirement (N)	Conclusion
1	83.5	46.6	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	93.9	42.0		
3	88.9	46.1		
4	94.7	43.3		
5	85.4	45.2		

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电话：020-37721161/66348638

Test Report

No: 21R002065MO

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	34.1		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	27.5			
3	32.2			
4	26.2			
5	40.4			

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电话：020-37721161/66348638

Test Report

No: 21R002065MO

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	92.4	44.2	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	90.7	46.0		
3	94.5	44.4		
4	94.3	44.8		
5	94.3	47.6		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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Test Report

No: 21R002065MO

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	36.9		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	29.0			
3	28.3			
4	39.6			
5	35.1			

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电话：020-37721161/66348638

Test Report

No: 21R002065MO

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: 20.0℃, relative humidity: 65.0%
Test area: 10cm^2

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	138	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	182		
3	144		
4	138		
5	135		

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Test Report

No: 21R002065MO

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: 20.0℃，relative humidity: 65.0%
Test area: 10cm^2

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	128	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	140		
3	136		
4	175		
5	175		

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Test Report

No: 21R002065MO

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: $10cm^2$

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	172	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	188		
3	166		
4	158		
5	150		

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Test Report

No: 21R002065MO

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: $10cm^2$

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	158	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	123		
3	146		
4	172		
5	144		

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Test Report

No: 21R002065MO

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℃， relative humidity: 65.1%
Face side tested
Temperature of the water: 20.0℃
Rate of increasing water pressure: 10cmH_2O/min

Results:

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	77.5	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	70.0		
3	70.5		
4	73.5		
5	72.5		

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Test Report

No: 21R002065MO

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℃， relative humidity: 65.1%
Face side tested
Temperature of the water: 20.0℃
Rate of increasing water pressure: 10cmH_2O/min

Results:

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	65.5	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	70.0		
3	64.0		
4	72.5		
5	77.0		

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Test Report

No: 21R002065MO

Cleanliness-microorganism
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/100cm²)	Requirement (CFU/100cm²)	Conclusion
1	58	≤300 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	64		
3	59		
4	76		
5	70		

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Test Report

No: 21R002065MO

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℃, 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: 2.0×10^{8} CFU/g

Results:

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

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Test Report

No: 21R002065MO

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℃, 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: 2.0×10^{8} CFU/g

Results:

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

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Test Report

No: 21R002065MO

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℃, 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: 2.0×10^{4} CFU/ml

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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Test Report

No: 21R002065MO

Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.1	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.0		
3	4.1		
4	4.0		
5	4.1		

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Test Report

No: 21R002065MO

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℃, 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: 2.0×10^{4} CFU/ml

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电话:020-37721161/66348638

Test Report

No: 21R002065MO

Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.0	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.0		
3	4.1		
4	4.0		
5	4.0		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
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Test Report

No: 21R002065MO

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: 20.0℃, 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	3.1	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	3.0		
		3	3.1		
		4	3.0		
		5	2.9		
	B: face	1	3.1		
		2	2.9		
		3	2.9		
		4	3.0		
		5	3.0		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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Test Report

No: 21R002065MO

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: 20.0℃, 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	3.1	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	3.1		
		3	3.1		
		4	3.0		
		5	3.0		
	B: face	1	2.7		
		2	2.9		
		3	2.9		
		4	2.9		
		5	2.7		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

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