Test Report

(Electronic version)

Verification Code: RHGA-2702-34
Verification Website: www.gttc.net.cn

No:21R001846 Issue Date: 2021-07-20

Applicant: YINGTAI (SUZHOU) MEDICAL TECHNOLOGY CO., LTD.
Address: NO. 390, YONGJIN ROAD, MIAOQIAO, TANGQIAO TOWN, ZHANGJIAGANG CITY, JIANGSU PROVINCE, CHINA.

Information confirmed by applicant:

Disposable isolation gown

Quantity: 16 pieces

Size: YTDIG001

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: 2021-07-10

Conclusion:

Breaking strength(dry state)[Material]	M
Breaking strength(dry state)[Sleeve seam]	M
Static hydrostatic resistance[Material]	M
Static hydrostatic resistance[Sleeve seam]	M
Cleanliness-microorganism	M

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

Remark:
Tested and judged by EN 13795-1:2019 as per client's requirement.
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: Yuan Liu

Yuan Liu Engineer

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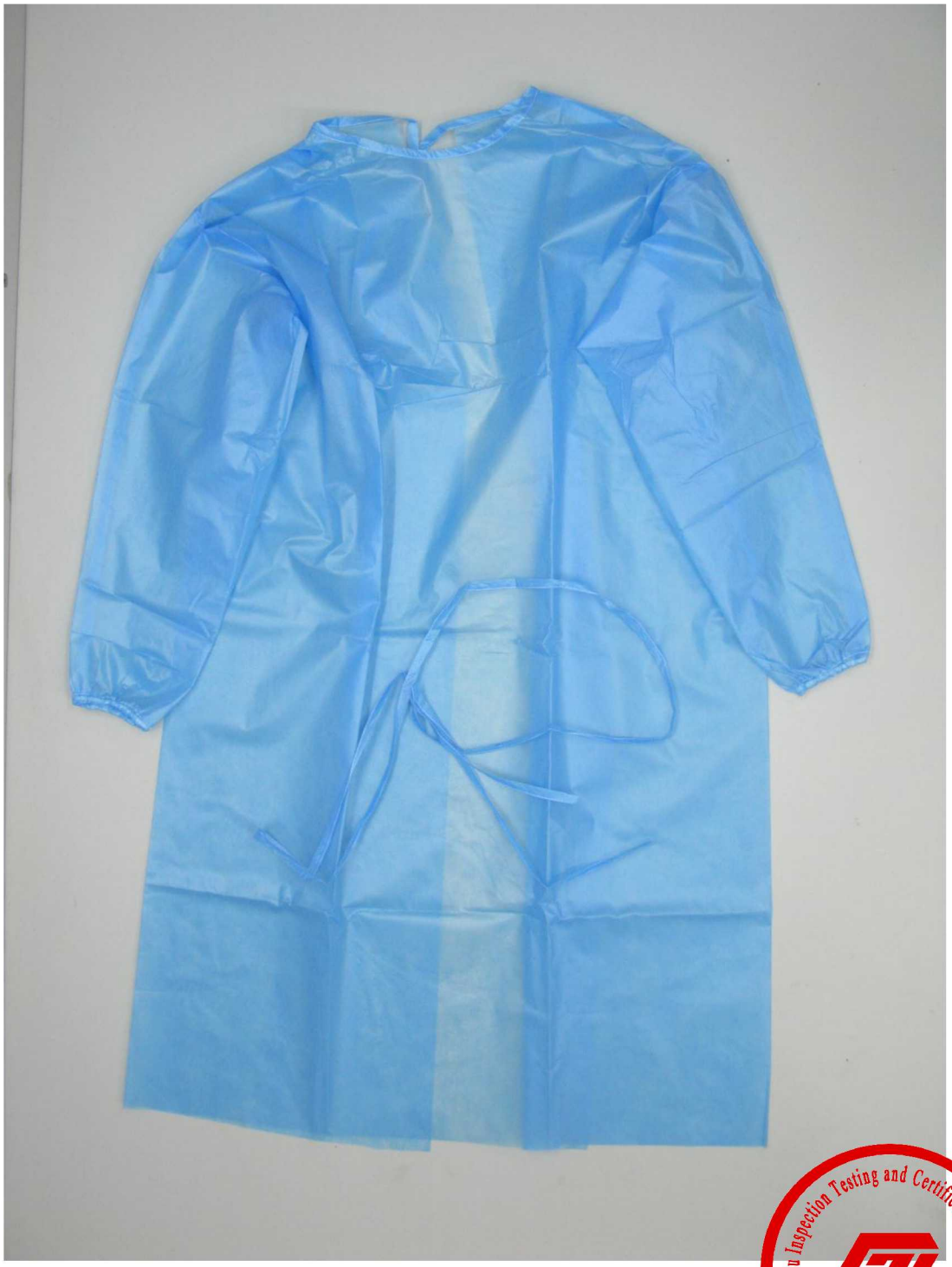

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Breaking strength（dry state）[Material]
Test Method: EN 29073-3:1992

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

Results:

Sample	MD (N)	CD (N)	Requirement (N)	Conclusion
1	60.0	35.4	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	59.9	35.2		
3	58.6	37.0		
4	54.6	36.4		
5	55.1	33.2		

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Test Report

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No: 21R001846

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	24.9		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	26.9			
3	24.7			
4	26.0			
5	20.4			

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No: 21R001846

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	114	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	104		
3	122		
4	120		
5	119		

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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	35.5	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	39.0		
3	48.5		
4	48.0		
5	43.5		

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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/100cm^2)	Requirement (CFU/100cm^2)	Conclusion
1	196	≤300 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	180		
3	160		
4	147		
5	175		

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End of Report

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