

RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO.,LTD
HESHAN INDUSTRY PARK, DONGGANG DISTRICT, RIZHAO, SHANDONG PROVINCE, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Surgical gown standard performance

Composition : (A)SMS 45g

Sample Color : (A)blue

Style No. : SQ-G5001

Manufacturer : RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO.,LTD

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Oct 09, 2020

Testing Period : Oct 10, 2020 - Nov 10, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).



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t (86-21) 61402666 f (86-21) 64958763
t (86-21) 61402666 f (86-21) 64958763

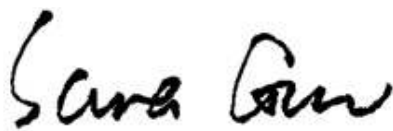
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Comment:

Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns (EN 13795-1:2019)	(A)
Clause 4 Bursting strength-Dry	M
Clause 4 Bursting strength-Wet	M
Clause 4 Tensile strength-Dry	M
Clause 4 Tensile strength-Wet	M
Clause 4 Liquid penetration-Water Resistance	M
Clause 4 Cleanliness microbial/Bioburden	M
Clause 4 Microbial Penetration-Dry	M
Clause 4 Microbial penetration-Wet	M
Clause 4 Particle release	M

Remark: M=Meet EN 13795-1:2019 standard performance requirement

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center



Sara Guo (Account Executive)



Dongjing Liu (Authorized Signatory)



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Test Result

Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns (EN 13795-1:2019)

Clause 4 Bursting strength-Dry*

(EN ISO 13938-1: 1999; Dry state; Test area: 10cm²)

Material

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	132	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	123		
3	126		
4	119		
5	127		

Sleeve seam

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	178	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	175		
3	199		
4	183		
5	186		



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Clause 4 Bursting strength-Wet*

(EN ISO 13938-1: 1999; Wet state; Test area: 10cm²)

Material:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	102	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	116		
3	134		
4	122		
5	127		

Sleeve seam:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	187	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	210		
3	199		
4	189		
5	178		



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Clause 4 Tensile strength-Dry

(EN 29073-3:1992; Dry state; The distance between the clamps: 200mm; Rate: 100mm/min)

(EN 29073-3:1992 eqv ISO 9073-3:1989)

Material

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	59.0	104.9	≥ 20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	57.7	121.7		
3	60.2	105.9		
4	55.2	108.3		
5	60.8	112.7		

Sleeve seam

Sample	(N)	Requirement (N)	Conclusion
1	36.7	≥ 20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	37.6		
3	41.2		
4	39.0		
5	38.5		



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Clause 4 Tensile strength-Wet

(EN 29073-3: 1992; Wet state. The distance between the clamps: 200mm; Rate: 100mm/min)

(EN 29073-3:1992 eqv ISO 9073-3:1989)

Material

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	57.3	121.7	≥20	Pass
2	58.1	120.0	(Surgical gown: standard performance critical product area)	
3	59.0	115.3		
4	61.2	111.1		
5	57.1	116.1		
			EN 13795-1:2019	

Sleeve seam

Sample	(N)	Requirement (N)	Conclusion
1	35.9	≥20	Pass
2	34.3	(Surgical gown: standard performance critical product area)	
3	44.7		
4	32.4		
5	37.1		
		EN 13795-1:2019	



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Clause 4 Liquid penetration-Water Resistance

(EN ISO 811: 2018; Rate of increase of water pressure: 10cm/min; temp. of distilled water: 20.0°C; Face side to water)

Material

Sample	Measured value (cmH ₂ O)	Requirement (cmH ₂ O)	Conclusion
1	> 20	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	> 20		
3	> 20		
4	> 20		
5	> 20		

Sleeve seam

Sample	Measured value (cmH ₂ O)	Requirement (cmH ₂ O)	Conclusion
1	> 20	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	> 20		
3	> 20		
4	> 20		
5	> 20		

Clause 4 Cleanliness microbial/Bioburden

(EN ISO 11737-1: 2018; Membrane Filtration Method)

Sample	total plate count (CFU/100cm ²)	Requirement (CFU/100cm ²)	Conclusion
1	96	≤300 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	102		
3	132		
4	114		
5	108		



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Clause 4 Microbial Penetration-Dry*

(EN ISO 22612:2005, The fourth generation of spores of bacillus subtilis ATCC 9372, The concentration of the spores: 1.8×10^8 CFU/g talcum powder, Sample: 12, Vibration frequency: 20800 times/min, Vibration time: 30min)

Material

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

Sleeve seam

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



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Clause 4 Microbial penetration-Wet*

(EN ISO 22610:2006, Temp: 24.5°C, RH: 56.0%, The distance of agar to plates brim: 3mm, Carrier material: 30µm polyurethane (PU))

Material

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.5	≥ 2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.4		
3	4.5		
4	4.5		
5	4.3		

Sleeve seam

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.3	≥ 2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.3		
3	4.3		
4	4.4		
5	4.4		



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Clause 4 Particle release*

(EN ISO 9073-10: 2004; Size of particles counted: 3µm-25µm)

(EN ISO 9073-10:2004 idt ISO 9073-10:2003)

Material

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	2.5	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	2.7		
		3	2.6		
		4	2.7		
		5	2.6		
	A: Back	1	2.8		
		2	2.7		
		3	2.7		
		4	2.7		
		5	2.8		

Sleeve seam

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	2.6	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	2.7		
		3	2.6		
		4	2.7		
		5	2.7		
	A: Back	1	2.7		
		2	2.8		
		3	2.7		
		4	2.8		
		5	2.7		

*This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment).



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Sample Photo



Face

Back

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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