

Test Report

(Electronic version)

Verification Website: www.gtgc.net.cn

Verification Code: JKUI-7349-14

No:20R000584

Issue Date: 2020-04-23

Information confirmed by applicant:

Disposable surgical gown

Quantity: ten pieces

Size: L standard type L

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: 2020-04-13

Conclusion:

CLEANLINESS-MICROORGNISM[SHELL]	M
THE RESISTANCE TO DRY MICROBIAL PENETRATION[SHELL]	M
STATIC HYDROSTATIC RESISTANCE[SHELL]	M
BREAKING STRENGTH[SHELL]	M
LINT AND OTHER PARTICLES GENERATION IN THE DRY STATE[SHELL]	M
BURSTING STRENGTH[SHELL]	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).

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

Approved By:

ZiShan Guo

ZiShan Guo Senior Engineer



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CLEANLINESS-MICROORGNISM (CFU/100cm²) [SHELL]

(EN ISO 11737-1:2018, MEMBRANE FILTRATION METHOD)

	TOTAL	REQUIREMENT
	1# 1	≤300
	2# 2	(LESS CRITICAL PRODUCT AREA OF SURGICAL
	3# 2	GOWN STANDARD PERFORMANCE)
	4# 0	(EN 13795-1:2019)
	5# 2	

THE RESISTANCE TO DRY MICROBIAL PENETRATION (CFU) [SHELL]

(EN ISO 22612:2005, THE FOURTH GENERATION OF SPORES OF BACILLUS SUBTILIS ATCC 9372, SPORE CONCENTRATION:1.9×10⁸ CFU/g TALCUM POWDER, SAMPLE:12, VIBRATION FREQUENCY: 20800times/min, VIBRATION TIME:30min)

		REQUIREMENT
	1# 3	≤300
	2# 3	(LESS CRITICAL PRODUCT AREA OF SURGICAL
	3# 2	GOWN STANDARD PERFORMANCE)
	4# 0	(EN 13795-1:2019)
	5# 0	
	6# 3	
	7# 2	
	8# 1	
	9# 1	
	10# 1	

STATIC HYDROSTATIC RESISTANCE (cmH₂ O) [SHELL]

(EN ISO 811:2018, STEADILY INCREASING WATER PRESSURE:10cmH₂ O/min, TEMPERATURE OF THE WATER:20.2℃ ,FACE DOWN AND FACE SIDE TESTED)

		REQUIREMENT
1#	80.0	≥10
2#	76.5	(LESS CRITICAL PRODUCT AREA OF SURGICAL
3#	72.5	GOWN STANDARD PERFORMANCE)
4#	81.0	(EN 13795-1:2019)
5#	84.5	

BREAKING STRENGTH (N) [SHELL]

(EN 29073-3:1992, DRY STATE, THE DISTANCE BETWEEN THE CLAMPS:200mm, RATE:100mm/min)

		REQUIREMENT
LENGTH	1# 104.9	LENGTH ≥20
	2# 108.4	
	3# 105.0	
	4# 104.0	
	5# 99.8	
WIDTH	1# 55.6	WIDTH ≥20 (LESS CRITICAL PRODUCT AREA OF SURGICAL GOWN STANDARD PERFORMANCE) (EN 13795-1:2019)
	2# 56.3	
	3# 58.3	
	4# 53.8	
	5# 59.8	



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LINT AND OTHER PARTICLES GENERATION IN THE DRY STATE[SHELL]

(EN ISO 9073-10:2004, SIZE OF PARTICLES COUNTED:3 μm~25 μm)
 (EN ISO 9073-10:2004 IDT ISO 9073-10:2003)

COEFFICIENT OF LINTING:

A: FACE 1# 1.6
 2# 1.8
 3# 1.8
 4# 1.7
 5# 1.7
 B: FACE 1# 1.3
 2# 1.5
 3# 1.5
 4# 1.5
 5# 1.7

REQUIREMENT

COEFFICIENT OF LINTING:
 ≤4.0
 (LESS CRITICAL PRODUCT AREA OF SURGICAL
 GOWN STANDARD PERFORMANCE)
 (EN 13795-1:2019)

BURSTING STRENGTH(kPa) [SHELL]

(EN ISO 13938-1:1999, DRY STATE, TEST AREA:10cm²)

1# 115
 2# 117
 3# 108
 4# 121
 5# 124

REQUIREMENT

≥40
 (LESS CRITICAL PRODUCT AREA OF SURGICAL
 GOWN STANDARD PERFORMANCE)
 (EN 13795-1:2019)



————End of Report————

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