

Test Report

(Electronic version)

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No: **20R000423**

Issue Date: 2020-04-17

Applicant: HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD
 Address: NO.6 BUILDING JINGXIANG ENERGY,NO.55 XIAGUANG EAST ROAD,GAOXIN DISTRICT,XIANGTAN,HUNAN

Information confirmed by applicant:
 Medical disposable protective coverall
 Quantity: ten pieces
 Type: One-piece Type XL/175

Standard Adopted:
 EN 13795-2:2019 <Surgical clothing and drapes> Requirements and test methods. Part 2 : Clean air suits>

Date Received/Date Test Started: 2020-04-06

Conclusion:

CLEANLINESS-MICROORGNISM[SHELL]	M
THE RESISTANCE TO DRY MICROBIAL PENETRATION[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).
 Copies of the report are valid only re-stamped.
 The experiment was carried out at No.1, Zhenjiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: *ZiShan Guo*
ZiShan Guo Senior Engineer



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

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

	REQUIREMENT
1# 3	≤100
2# 1	(STANDARD PERFORMANCE)
3# 0	(EN 13795-2:2019)
4# 2	
5# 1	

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

(EN ISO 22612:2005, THE FOURTH GENERATION OF SPORES OF BACILLUS SUBTILIS ATCC 9372, SPORE CONCENTRATION:1.7×10⁸ CFU/g TALCUM POWDER, SAMPLE:12, VIBRATION FREQUENCY:20800 times/min, VIBRATION TIME:30min)

	REQUIREMENT
1# 0	≤100
2# 0	(STANDARD PERFORMANCE)
3# 0	(EN 13795-2:2019)
4# 0	
5# 0	
6# 0	
7# 0	
8# 0	
9# 0	
10# 0	

BREAKING STRENGTH(N) [SHELL]

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

	REQUIREMENT
LENGTH:	≥20
1# 39.2	(STANDARD PERFORMANCE)
2# 36.6	(EN 13795-2:2019)
3# 41.2	
4# 39.3	
5# 39.0	
WIDTH:	
1# 79.8	
2# 86.9	
3# 84.6	
4# 85.2	
5# 93.8	



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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)

COEF OF LINTING:

A FACE:
1# 2.2
2# 2.2
3# 2.1
4# 2.2
5# 2.0
B FACE:
1# 2.3
2# 2.2
3# 2.2
4# 2.1
5# 2.1

REQUIREMENT

COEF OF LINTING:
≤4.0
(STANDARD PERFORMANCE)
(EN 13795-2:2019)

BURSTING STRENGTH(kPa) [SHELL]

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

1# 102
2# 95.7
3# 91.3
4# 106
5# 94.2

REQUIREMENT

≥40
(STANDARD PERFORMANCE)
(EN 13795-2:2019)

—End of Report—



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