

Production Area



Cutting Area



CPE Blow Molding



Manufacturing Packing

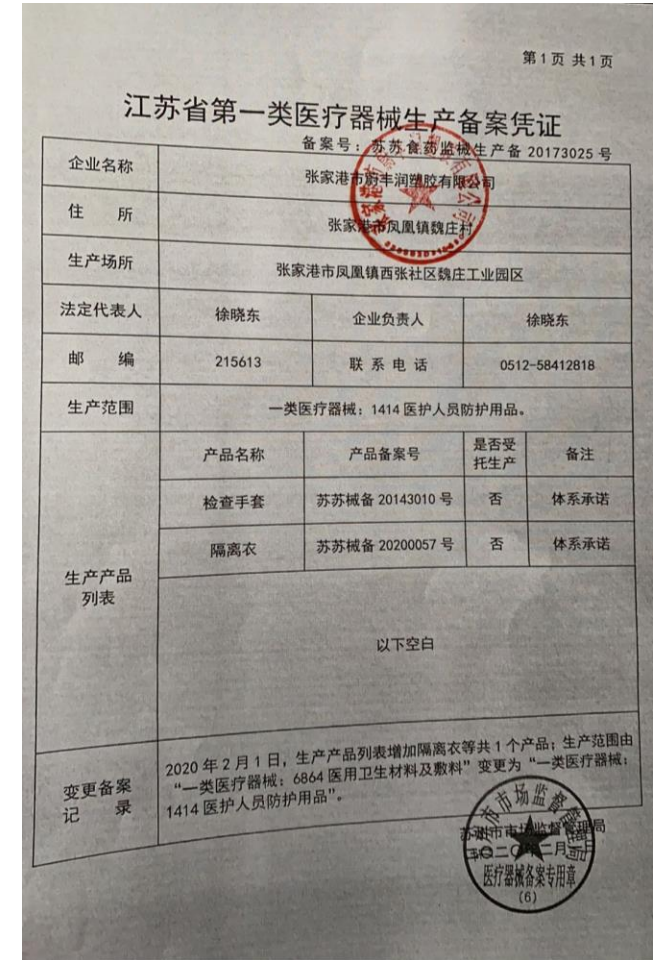
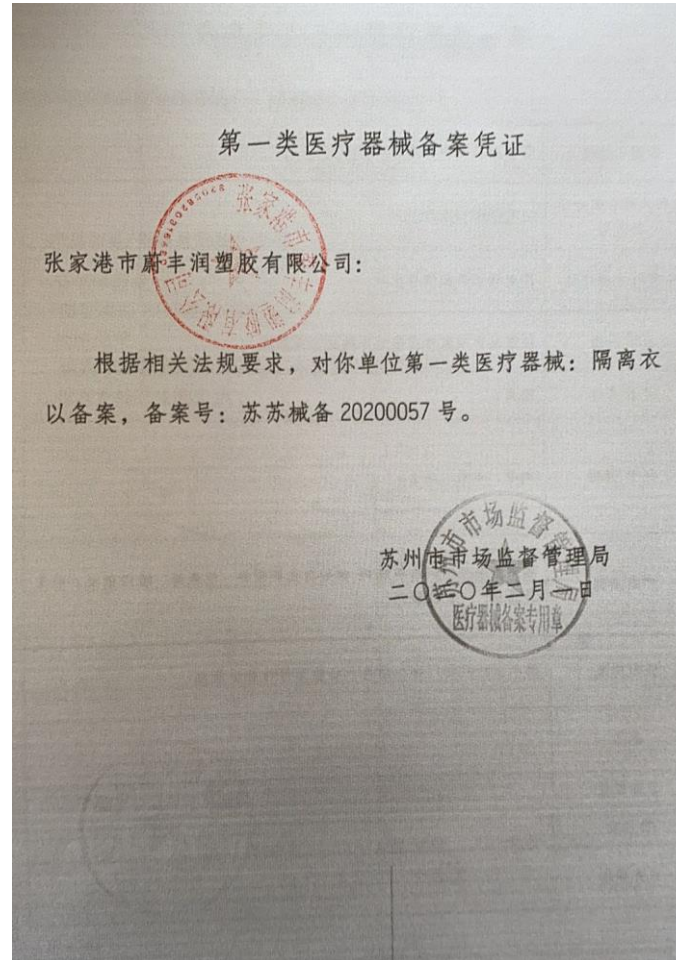


1pc individual packing



US Customer Level 4 Label

Manufacture Class 1 Medical Certifications



AAMI Level 3 SGS Report



Test Report **SL52025244735801TX** Date: April 26, 2020 Page 1 of 3
 WUXI(AMERICA)TECHNOLOGY IMPORTING & EXPORTING CO LTD
 NO 1288-305, GUANGRUI ROAD, WUXI CITY, JIANGSU, CHINA

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

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

Sara Guo

Sara Guo (Account Executive)



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Test Result

Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities
 (ANSI/AAMI PB70-2012)

Section 4.2.1 Water Resistance: Impact Penetration Test
 (AATCC 42-2017)

Isolation gown

As received

Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	0.0	0.0	0.0	0.0	0.0
Area B (Critical zone-sleeve)	0.0	0.0	0.0	0.0	0.0
Area C (Critical zone-back)	0.0	0.0	0.0	0.0	0.0

Remark:

- Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5grams(g)
- Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)
- Level 3: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)

Section 4.2.1 Water Resistance: Hydrostatic Pressure Test
 (AATCC 127-2018; Hydrostatic Head; Rate of increase of water pressure:60mbar/min; temp. of distilled water: 21°C, fabric face side of water)

Isolation gown

As received

Water Column (cmH ₂ O)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	>50.0	>50.0	>50.0	>50.0	>50.0
Area B (Critical zone-sleeve)	>50.0	>50.0	>50.0	>50.0	>50.0
Area C (Critical zone-back)	>50.0	>50.0	>50.0	>50.0	>50.0

Remark:

- Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH₂O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH₂O



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Barrier performance of each component and final classification commended.

Isolation gown

	Impact Penetration Test AATCC 42/g	Hydrostatic Pressure Test AATCC 127/cmH ₂ O	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (critical zone-front)	0.0	>50.0	/	Level 3	Level 3
Area B (critical zone-sleeve)	0.0	>50.0	/	Level 3	
Area C (Critical zone-back)	0.0	>50.0	/	Level 3	

Remark:

- The barrier performance of all critical zone components, including seams and points of attachments, shall be determined. The classification of isolation gown shall be a number denoting the performance of the critical zone component having the lower barrier performance.
- Level 1: Impact Penetration Test-AATCC 42: ≤4.5g;
- Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127:≥20cmH₂O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127:≥50cmH₂O;
- Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.

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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Product Specification & FDA CODE

		Item number: CPG-1 PE apron	
Features: Material: PE 23gsm Single-use CPE ISOLATION GOWN 43-45g latex free ,Thumb button FDA test 1 pc Individual Poly Bag Packing			
Details:		Country of Origin: China Factory FOB Point: Shanghai HTS#: 392620900 Duty Rate: Lead time: 15-20 days	
Product Dimensions:	180*110cm	Price: FOB China Quotation date: May 2nd, 2020	
Units per bag:	20		
Inner box:	/		
Weight:	40g		
Master packaging:	57*37*29cm		
Units per Master	200		
Gross weight	8.5kg		
Net weight	8kg		

FDA

FDA Class 1 Operator Number 10072371

FDA Code – OEA

Category Name: Non-Surgical Isolation Gown

ZHANGJIAGANG WEIFENGRUN PLASTIC CO., LTD.

Quality Inspection

AQL Level 1 Example 200k, Sample Size 315pcs

Critical	Major	Minor
0.65	1.5	4.0
AC RE	AC RE	AC RE
5 6	10 11	21 22