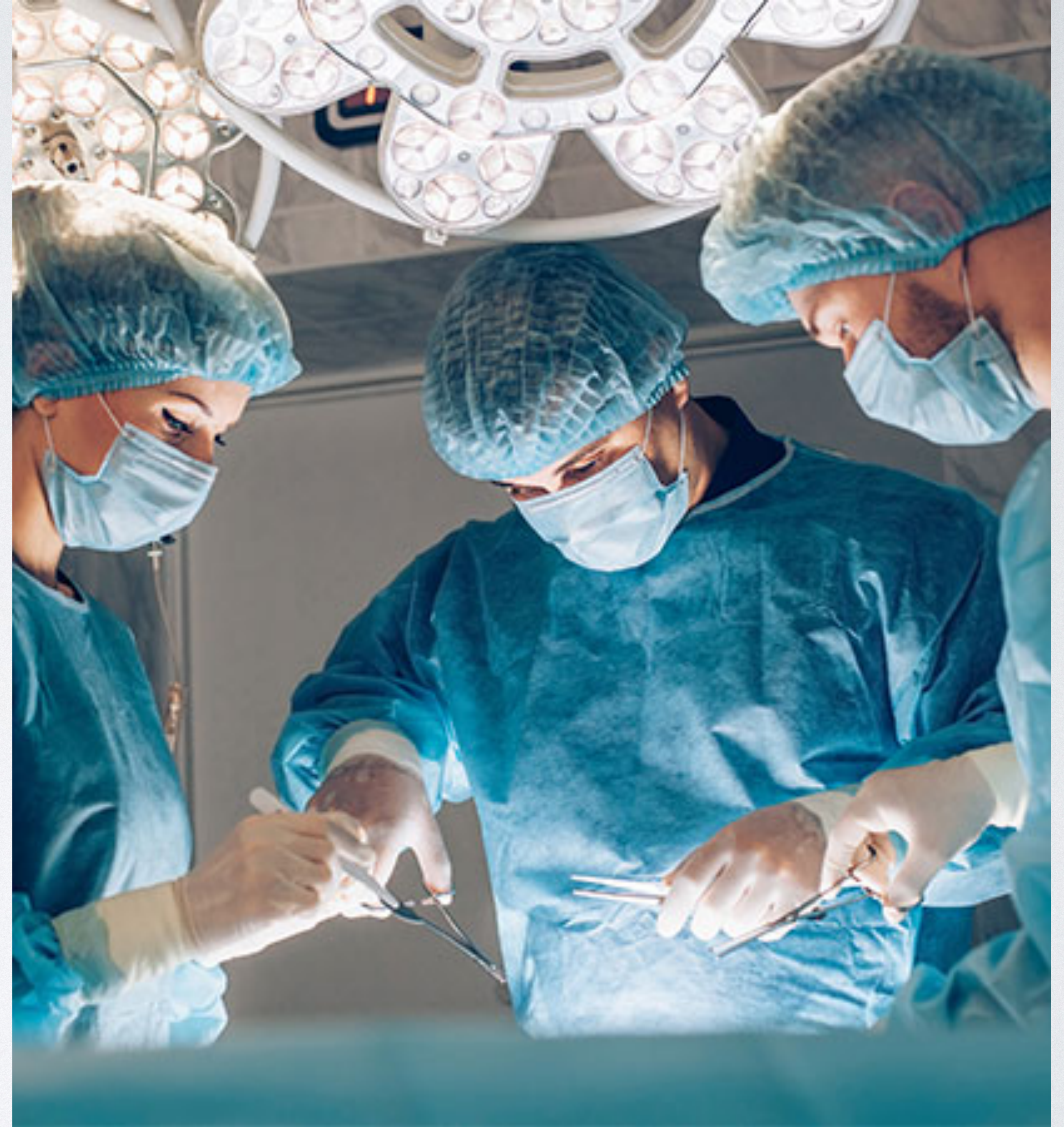


# ISOLATION GOWNS

Globus Global Manufacturing  
&  
Trading Co Limited





**Fiscal Year 2020**  
**FDA REGISTRATION CERTIFICATE**  
**FDA注册证明**

This certifies that:

**YIWU TIANZI BAGS & CASES COMPANY. LTD**  
**No.55 Suhua Street Suxi Town yiwu, ZHEJIANG, 322000,**  
**CHINA**

has completed the FDA Establishment Registration and Device Listing  
with the US Food & Drug Administration

**Owner/Operator Number: 10071389**

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable protective mask	QKR	1	D395298	Manufacturer
DISPOSABLE gowns level 1 DISPOSABLE gowns level 2	OEA	1	D398561	Manufacturer

This is a formal notice upon your company that your product applied has been successfully registered by the U.S. Food and Drug Administration. The registration remains effective unless the said registration is terminated by the U.S. Food and Drug Administration. We makes no other representations or warranties, nor does this certificate make sole benefit as it is issued. This notice does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. We assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. We are not affiliated with the U.S. Food and Drug Administration.

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Jimmy engineer

Issued: April. 30 2020

Expiration Date: Dec31, 2020

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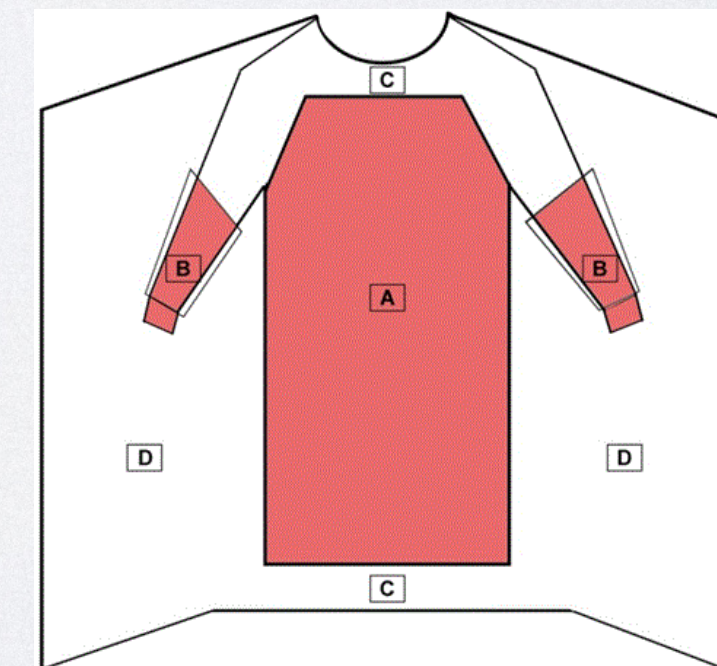
e-mail: [webmail@oc.fda.gov](mailto:webmail@oc.fda.gov)



# Disposable Gowns Specification

	Level 1 (Visitors cover)	Level 1	Level 2	Level 3
Specification	Disposable Isolation Gown- <u>Level 1</u> - <b>20 GSM</b> - <b>Size:</b> M-XXL - Unisex - Long sleeves With elastic cuffs. - Fluid Barrier Protection/ resistant - PP - Neck and waist Ties - Full back - Elastic Closure Cuffs * <b>Natural Rubber and Latex free</b>	Disposable Isolation Gown- <u>Level 1</u> - <b>30 GSM</b> - <b>Size:</b> M-XXL - Unisex - Long sleeves With elastic cuffs. - Fluid Barrier Protection/ resistant - PP+PE/ SMS / PP - Neck and waist Ties - Full back - Elastic Closure Cuffs * <b>Natural Rubber and Latex free</b>	Disposable Isolation Gown- <u>Level 2</u> - <b>45 GSM</b> - <b>Size:</b> M-XXL - Unisex - Long sleeves With elastic cuffs. - Fluid Barrier Protection/ resistant - PP+PE/ SMS / PP - Neck and waist Ties - Full back - Elastic Closure Cuffs * <b>Natural Rubber and Latex free</b>	Disposable Isolation Gown- <u>Level 3</u> - <b>60 GSM</b> - <b>Size:</b> M-XXL - Unisex - Long sleeves With elastic cuffs. - Fluid Barrier Protection/ resistant - PP+PE/ SMS / PP - Neck and waist Ties - Full back - Elastic Closure Cuffs * <b>Natural Rubber and Latex free</b>

- \* Changes and special request are gladly accepted
- \* We supply all Gowns type to all need





# Isolation Disposable Gowns main use according to levels

Gowns Level Use Details					
Type of PPE	Feature Tested	Standard Designation	Sub headings	Description	Applicability
Deposable Gowns	Liquid Barrier Performance	AAMI PB70:2012		Classifies a gown's ability to act as a barrier to penetration by liquids or liquid-borne pathogens based on four levels. The critical protective zones for surgical and non-surgical gowns are defined differently by the standard. While the critical zones designate different protective areas for the different gowns, the levels of protection are the same for both surgical and non-surgical	Liquid barrier performance is not related to the strength of the material. This standard references several other standards
			Level 1	Level 1: Minimal risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit	basic care, standard hospital medical unit
			Level 2	Level 2: Low risk, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab	Blood draw from a vein, Suturing, Intensive care unit, Pathology lab
			Level 3	Level 3: Moderate risk, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases	Arterial blood draw, Inserting an IV, Emergency Room, Trauma
			Level 4	Level 4: <i>High risk</i> , to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne)	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods



## Isolation Gowns Size:

Size	S	M	L	XL	XXL
Centimeters	115x137	120x140	130x150	140x145	150x160
Inch	4.3x54	47x55	51.2x59	55x57	59x63
Feet	3.77x4.5	3.93x4.59	4.26x4.92	4.59x4.75	4.92x5.24

- Clients experience tip on sizes:

“Take One size feet all,  
but make sure to take a big size”

Polypropylene(PP)  
Spunbond

SMS

Polyethylene  
Coated









# Understanding protection level test - What is AAMI PB70?

## Association for the Advancement of Medical Instrumentation (AAMI)

- \* Develop standards to support the healthcare community
- \* AAMI PB70 – Surgical Gowns/Drapes & Iso Gowns



## AAMI PB70 – Iso Gowns specifically

- \* 360° Protection (fabric, seams, tie attachment) – point of entry for fluids
- \* Developed to give the user a universal rating for fluid resistance
- \* Barrier Protection - 4 different levels



# AAMI LEVELS FOR ISOLATION GOWNS

	Level 1 💧	Level 2 💧💧		Level 3 💧💧💧	
Test	AATCC 42:2000 Impact penetration	AATCC 42:2000 Impact penetration	AATCC 127:1998 Hydrostatic Pressure	AATCC 42:2000 Impact penetration	AATCC 127:1998 Hydrostatic Pressure
Test definition AATCC	<u>AATCC 42</u> Measures the resistance of fabrics to the liquid penetration of water by impact.	<u>AATCC 42</u> Measures the resistance of fabrics to the liquid penetration of water by impact.	<u>AATCC 127</u> Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	<u>AATCC 42</u> Measures the resistance of fabrics to the liquid penetration of water by impact.	<u>AATCC 127</u> Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.
Requirements at 4% AQL	Water impact $\leq 4.5$ g	Spray impact $\leq 1.0$ g	Hydrostatic Pressure $\geq 20$ cm	Spray impact $\leq 1.0$ g	Hydrostatic pressure $\geq 50$ cm
Anticipated Risk of Exposure	Low	Moderate		Moderate to High	

AAMI PB70 – Iso Gowns specifically

- ◆ 360° Protection (fabric, seams, tie attachment) – point of entry for fluids
- ◆ Barrier Protection - 4 different levels





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Date : 2020-05-08

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## TESTREPORT

### Test information

Applicant	:	YIWU TIANZI BAGS AND CASES CO.,LTD.
Address	:	N0.55 SUHAU STR., SUXI INDUSTRIAL AREA,YIWU,ZHEJIANG.
Sample Description	:	20gPP+20gPE isolation gown.
Country of origin	:	China.
Receiving Date	:	May 05, 2020.
Test period	:	May 05, 2020. ~ May 08, 2020.
Test Requested	:	Tests requested in accordance to client requirement.

TEST ITEMS	CONCLUSION
GB 18401-2010 National general safety technical code for textile products - Formaldehyde Content	PASS
GB 18401-2010 National general safety technical code for textile products - pH Value	PASS
GB 18401-2010 National general safety technical code for textile products – Determination of Odour	PASS
GB 18401-2010 National general safety technical code fortextile products - Color Fastness to Crocking	PASS
GB 18401-2010 National general safety technical code for textile products – Color Fastness to Perspiration	PASS
GB 18401-2010 National general safety technical code for textile products – Color Fastness to Water	PASS
GB 18401-2010 National general safety technical code for textile products - AZO Colorants	PASS
Section 4.2.1 Water Resistance: Impact Penetration Test - Client's requirement	PASS
Hydrostatic Pressure Test - Client's requirement	PASS

Signed for and on behalf of  
RTS TEST CO., LTD. (Zhejiang)



CHANGBIAO YU

Approved signatory

Zhejiang RTS Test Co., LTD.  
Phone: +86(0)579-85640080  
Email: [ruyi-8@zj-rtz.com](mailto:ruyi-8@zj-rtz.com)

<http://www.rtslab.com> 浙江省义乌市稠江街道英才创业园 B 区 7 幢 2-4 层.  
2-4/f, Building 7, Block B, Ying cai Business Park, Choujiang Street, Yiwu, Zhejiang.



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Date : 2020-05-08

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### Sample image:



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**A. Formaldehyde content test:** (Unit: mg/kg)

Test Method: GB/T 2912.1-2009, determined colorimetrically by UV-VIS spectroscopy.

Test Number	Item/ component description(s)			
A1	20gPP+20gPE isolation gown			
Test Item	MDL	Test result A1	Requirement	Conclusion
Formaldehyde	20	N.D.	75	PASS

Note:

- 1) MDL=Method Detection Limit.  
2) N.D. = not detected, less than MDL.  
3) “▲”=This data is obtained from composite testing on more than one materials, it is possible that result obtained from individual testing on any one of the materials is substantially higher. Please be cautious when using this data for compliance evaluation.

**B. pH Value:**

Test Method: GB/T 7573-2009

Test Number	Item/ component description(s)		
A1	20gPP+20gPE isolation gown		
Test Item	Test result A1	Requirement	Conclusion
pH Value	7.3	4.0~8.5	PASS

Note:

- 1)“▲” = This data is obtained from composite testing on more than one materials or shapes or shapes, it is possible that result obtained from individual testing on any one of the materials or shapes is substantially higher. Please be cautious when using this data for compliance evaluation.



**C. Odour:**

Test Method: GB 18401-2010 section 6-7

Test Number	Item/ component description(s)
A1	20gPP+20gPE isolation gown
Test Item	Test result A1
Odour	Odorless

Remark: No odour from mould, high boiling fraction of petrol, fish, aromatic hydrocarbons or perfume.

**D. Color Fastness to Crocking:** (Unit: Grade)

Test Method: GB/T 3920-2008

Test Number	Item/ component description(s)		
A1	20gPP+20gPE isolation gown		
Test item(s)		Test result A1	Requirement
Length	Dry	4-5	≥3
Conclusion:		PASS	--

Note:

Explanation of colorfastness results:

- Grade 5    negligible or no change or staining  
Grade 4    slightly changed or stained  
Grade 3    noticeably changed or stained  
Grade 2    considerably changed or stained  
Grade 1    much changed or heavily stained

**E. Color Fastness to Perspiration:** (Unit: Grade)

Test Method: GB/T 3922-2013

Test Number	Item/ component description(s)		
A1	20gPP+20gPE isolation gown		
Test item	Test result A1	Requirement	Conclusion

Zhejiang RTS Test Co., LTD.





Acid	Color Change	4-5	≥3	PASS
	Color Staining	--	--	--
	Acetate	4-5	≥3	PASS
	Cotton	4-5	≥3	PASS
	Nylon	4-5	≥3	PASS
	Polyester	4-5	≥3	PASS
	Acrylic	4-5	≥3	PASS
	Wool	4-5	≥3	PASS
Alkali	Color Change	4-5	≥3	PASS
	Color Staining	--	--	--
	Acetate	4-5	≥3	PASS
	Cotton	4-5	≥3	PASS
	Nylon	4-5	≥3	PASS
	Polyester	4-5	≥3	PASS
	Acrylic	4-5	≥3	PASS
	Wool	4-5	≥3	PASS

**Note:**  
**Explanation of colorfastness results:**  
Grade 5   negligible or no change or staining  
Grade 4   slightly changed or stained  
Grade 3   noticeably changed or stained  
Grade 2   considerably changed or stained  
Grade 1   much changed or heavily stained  
**F. Color Fastness to water:** (Unit: Grade)

**Test Method:** GB/T 5713-2013

Test Number	Item/ component description(s)		
A1	20gPP+20gPE isolation gown		
Test item	Test result A1	Requirement	Conclusion



Color Change	4-5	≥3	PASS
Color Staining	--	-	--
Acetate	4-5	≥3	PASS
Cotton	4-5	≥3	PASS
Nylon	4-5	≥3	PASS
Polyester	4-5	≥3	PASS
Acrylic	4-5	≥3	PASS
Wool	4-5	≥3	PASS

**Note:**  
**Explanation of colorfastness results:**  
Grade 5   negligible or no change or staining  
Grade 4   slightly changed or stained  
Grade 3   noticeably changed or stained  
Grade 2   considerably changed or stained  
Grade 1   much changed or heavily stained  
**G. AZO Colorants:** (Unit: mg/kg)

**Test Method:** GB/T 17592-2011, Analysis was preformed by GC-MS.

Test Number	Item/ component description(s)				
A1	20gPP+20gPE isolation gown				
No.	Forbidden	CAS No.	MDL	Limit	Test result A1
1	4-aminobiphenyl	92-67-1	5	20	N.D.
2	benzidine	92-87-5	5	20	N.D.
3	4-chloro-o-toluidine	95-69-2	5	20	N.D.
4	2-naphthylamine	91-59-8	5	20	N.D.
5	o-aminoazotoluene	97-56-3	5	20	N.D.
6	p-chloroaniline	106-47-8	5	20	N.D.
7	2,4-diaminoaniso	615-05-4	5	20	N.D.
8	4,4'-diaminobiphenymethane	101-77-9	5	20	N.D.
9	3,3'-dichlorobenzidine	91-94-1	5	20	N.D.





10	3,3'-dimethoxybenzidine	119-90-4	5	20	N.D.
11	3,3'-dimethylbenzidine	119-93-7	5	20	N.D.
12	3,3'-dimethyl-4,4'-diaminobiphenylmethane	838-88-0	5	20	N.D.
13	p-cresidine	120-71-8	5	20	N.D.
14	4,4'-methylene-bis-(2-chlorolaniline)	101-14-4	5	20	N.D.
15	4,4'-oxydianiline	101-80-4	5	20	N.D.
16	4,4'-thiodianiline	139-65-1	5	20	N.D.
17	o-toluidine	95-53-4	5	20	N.D.
18	2,4-toluylenediamine	95-80-7	5	20	N.D.
19	2,4,5-trimethylaniline	137-17-7	5	20	N.D.
20	o-anisidine	90-04-0	5	20	N.D.
21	4-aminoazobenzene	60-09-3	5	20	N.D.
22	5-nitro-o-toluidine	99-55-8	5	20	N.D.
23	2,4-Dimethylaniline	95-68-1	5	20	N.D.
24	2,6-Dimethylaniline	87-62-7	5	20	N.D.
Conclusion				--	PASS

**Note:**  
1) MDL=Method Detection Limit.  
2) N.D. = not detected, less than MDL.  
3) “▲”=This data is obtained from composite testing on more than one materials, it is possible that result obtained from individual testing on any one of the materials is substantially higher. Please be cautious when using this data for compliance evaluation.



**H. \*Section 4.2.1 Water Resistance: Impact Penetration Test:**

Test Method: AATCC 42-2017

Test Number	Item/ component description(s)				
A1	20gPP+20gPE 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	0.1	0.1	0.0	0.0
Area C (Critical zone-back)	0.0	0.1	0.0	0.0	0.0
Seam	0.0	0.1	0.1	0.1	0.1

Remark:0.0

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



End  
Of  
Test Report



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Date : 2020-05-08  
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Barrier performance of each component  
and final classification commended.

--	Impact Penetration Test AATCC 42 Hydrostatic	Pressure Test AATCC 127	Level	Final classification
Area A (Critical zone-front)	0.0g	26.5cmH <sub>2</sub> O	Level 2	Level 2
Area B (Critical zone-sleeve)	0.1g	25.8cmH <sub>2</sub> O	Level 2	
Area C (Critical zone-back)	0.1g	26.1cmH <sub>2</sub> O	Level 2	
Seam	0.1g	26.5cmH <sub>2</sub> O	Level 2	
Remark: 1) The entire isolation gown(areas A,B and C), including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1; 2) Level 1: Impact Penetration Test-AATCC 42: ≤ 4.5g; 3) Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH <sub>2</sub> O; 4) Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH <sub>2</sub> O; 5) Level 4: Resistance to Bacteriophage Phi-x174-ASTM F 1671: Pass.				

Note: Client's requirement: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH<sub>2</sub>O.

----- End of Report -----

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YIWU TIANZI BAGS AND CASES CO.,LTD.  
NO.55 SUHAU STR., SUXI INDUSTRIAL AREA,YIWU,ZHEJIANG.

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

Sample Description : (A)Isolation gown  
  
Composition : (A)SMS  
Sample Color : (A)blue  
Manufacturer : YIWU TIANZI BAGS AND CASES CO.,LTD.  
Supplier : YIWU TIANZI BAGS AND CASES CO.,LTD.  
  
Sample Receiving Date : Jun 16, 2020  
Testing Period : Jun 16, 2020 - Jun 18, 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).  
  
Test Performed : Selected test(s) as requested by applicant

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)

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
Seam between areas A&B	0.0	0.0	0.0	0.0	0.0
Seam between areas A&C	0.0	0.0	0.0	0.0	0.0
Seam between areas B&C	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)

As received

Water Column (cmH <sub>2</sub> 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
Seam between areas A&B	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas A&C	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas B&C	>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 20cmH <sub>2</sub> O ● Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH <sub>2</sub> O					



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### Barrier performance of each component and final classification commended

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH <sub>2</sub> 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	
Seam between areas A&B	0.0	>50.0	/	Level 3	
Seam between areas A&C	0.0	>50.0	/	Level 3	
Seam between areas B&C	0.0	>50.0	/	Level 3	
<b>Remark:</b> <ul style="list-style-type: none"> <li>● 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.</li> <li>● Level 1: Impact Penetration Test-AATCC 42: ≤4.5g;</li> <li>● Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH<sub>2</sub>O;</li> <li>● Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH<sub>2</sub>O;</li> <li>● Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.</li> <li>● Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.</li> </ul>					

# End Test Report



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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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- D. Giving timely information to the customers regarding trends of the market dynamics.
- E. Wake up every day with a smile :)



# Thank you

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