

Isolation Gowns Product Details

ISGC-32 – AAMI LEVEL 2 DISPOSABLE GOWN

ISGC-75 – Level 2 REUSABLE GOWN

ISGC-32 Disposable Gown



PRODUCT

ITEM#	PRODUCT	DESCRIPTION	MATERIAL	HOW TO WEAR	PACKING
ISGC-32	Level 2 Disposable Isolation Gown	<p>AAMI Level 2 ISOLATION GOWN WITH CUFF</p> <p>Breathable, flexible gown. Gowns are generously sized for full coverage and flexibility.</p> <p>Color: Blue or yellow depending on fabric availability</p> <p>Set in sleeve style</p> <p>White knit cuffs.</p> <p>Constructed with waist and neck ties to ensure secure fit.</p> <p>59 inches wide /48 inches long - OSFA</p>	<p>PP+PE,₃₂GS</p> <p>M 120X150</p>	<ol style="list-style-type: none"> 1. Wash your hands. 2. Take out of package and unfold. 3. Place each arm forward into gown 4. Tie gown at neck 5. Tie gown at waist 6. Wash your hands carefully <p>Life cycle: One time</p> <p>Validity: three years</p>	<p>Packaged: 10pc/polybag - 100pc/ctn</p> <p>Carton size: 65x39x21 59x38x45 grs wt: 10 kg</p>

Please note AAMI is a standard set by them . It is not a certificate. The certificate that is included in the isolation gowns ISO13485 follows the AAMI standards.

ISGC-75 Reusable Gown



PRODUCT

ITEM#	PRODUCT	DESCRIPTION	MATERIAL	HOW TO WEAR	PACKING
ISGC-75	Level 2 Reusable Isolation Gown	<p>AAMI Level 2 Washable Reusable Gown with Cuff</p> <p>Breathable, flexible gown. Gowns are generously sized for full coverage and flexibility.</p> <p>Color: Yellow with white ribbed cuffs</p> <p>Long Sleeve Reusable Gown</p> <p>Ragland style sleeve</p> <p>Back neck-tie</p> <p>Back waist tie 36"</p> <p>Machine washable / Reusable</p> <p>Cuffs have a safety stitch</p> <p>size is 59" L x 44.8" W</p> <p>OSFM</p>	95 gsm 100% soft polyester microfiber	<ol style="list-style-type: none"> 1. Wash your hands. 2. Take out of package and unfold. 3. Place each arm into arm hole access from the back of gown 4. Tie gown at neck 5. Tie gown at waist 6. Wash your hands carefully <p>Life cycle: Reusable</p> <p>Washing instructions shown below</p> <p>Validity: three years</p>	<p>Packaged:</p> <p>10pc/polybag - 100pc/ctn</p> <p>Carton size: 65x39x21</p> <p>59x38x45 grs wt: 10 kg</p>

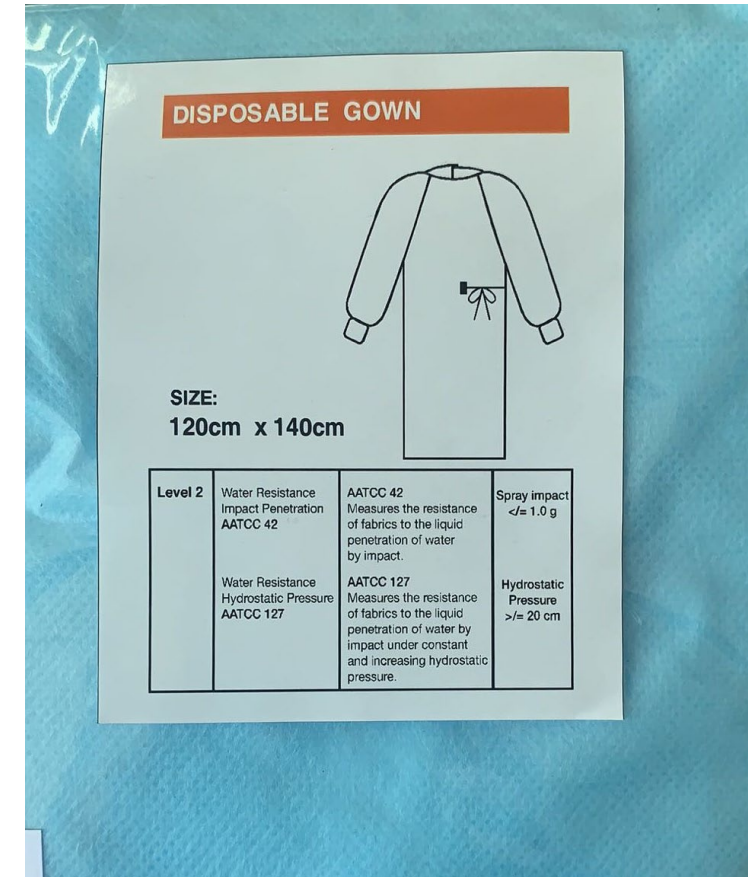
**Packaging for
ISGC-32
Level 2 isolation
Gown**

ISGC-32

Packaged: 10pc/polybag - 100pc/ctn

Carton size: 65x39x21

59x38x45 grs wt: 10 kg



FDA COMPLIANCE

Importer & Distributor: Baoding Taizhou
Paper Plastic Packing Co. LTD

Address: No,486, District 7, Daokou
Village, Zhugezhuang Town, Xiongan New
District, Hebei Province

FDA Registration Number: 10069945

Compliance:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

Baoding Taizhou Paper Plastic Packing Co., Ltd
No. 486, District 7, Daokou Village, Zhugezhuang Town,
Xiongan New District, Hebei Province

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

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10069945

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D391875	OEA	Non-Surgical Isolation Gown	barrier gown, integrated style TZ-M, integrated style TZ-L,integrated style TZ-XL,split type TZ-M,split type TZ-L,split type TZ-X

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

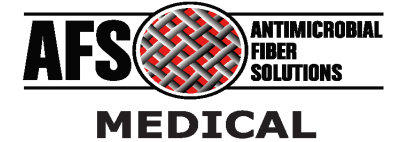
Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." 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, CCT is not affiliated with the U.S. Food and Drug Administration.

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Chief engineer
Issued: 04/13/2020
Expiration Date: 12/31/2020



Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov



Establishment Registration & Device Listing



FDA Home Medical Devices Databases

1 result found for Owner Operator Number :
10069945

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Establishment Name	Registration Number	Current Registration Yr
BAODING TAIZHOU PAPER PLASTIC PACKAGING CO.,LTD CHINA	No number listed	2020
<ul style="list-style-type: none"> Non-Surgical Isolation Gown - Barrier Gown, Integrated Style TZ-M, Integrated Style TZ-L, Integrated Style TZ-XL, Split Type TZ-M, Split Type TZ-L, Split 		Foreign Exporter; Manufacturer

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Level 2 Disposable Gown Tensile Test Report



Testing Report



Job No.:/


Report No.: HQ203051239-2

Date: June. 03, 2020

Applicant: Headwear Apparel CO.LTD
South of Xiaoyao village, Ligezhuang Town,
Jiaozhou, Qingdao, Shandong Province, China ,266300

Manufacturers: /

Overall Rating:	
Data	<input type="checkbox"/>
Satisfactory	<input checked="" type="checkbox"/>
Unsatisfactory	<input type="checkbox"/>
Others, See Detail Enclosed	<input type="checkbox"/>

Sample Information		
	Client:	/
	ID:	/
	Brand:	/
	Item No.:	/
	Description:	Disposable Isolation Gown
	Fiber Content:	/
	Safety Category:	/
	Received Date:	May. 18, 2020
	Testing Period:	May. 18, 2020 to May. 19, 2020
	Testing Standard:	Selected tests as requested by applicants, details refer to following pages.
Service Location:	Hangzhou	
Remark:	This Report is the English Version of the Test Report No. HQ203051239-1.	

To be Continued

Authorized by:
HQTS QA International Services Co., Ltd.



Neil Peng
Supervisor



Test Summary:

No.	Test Items	Criterion	Test Summary
1	Tensile Strength	GB/T 38462-2020 Level II	Pass
2	Bursting strength	GB/T 38462-2020 Level II	Pass
3	Fabric weight	/	/

*****To be Continued

Test Items	Test Standards	Criterion & Requirement	Test Result	Comments
Tensile Strength	GB/T 24218.3-2010	GB/T 38462-2020 Level II ≥20N	MD: 37.5N CD: 22.8N	Pass
Bursting Strength	GB/T 7742.1-2005 test area: 7.3cm ²	GB/T 38462-2020 Level II ≥40kPa	67.0kPa	Pass
Fabric Weight	GB/T 24218.1-2009	/	35g/m ²	/

Remark:

- 1) MD=Machine Direction; CD=Cross Direction
- 2) Tensile Strength and Fabric Weight Test Items is out of lab's CMA, CNAS Certification.

*****End of Report

Level 2 Disposable Gown Water Test Reports

委托方 Applicant	保定泰舟纸塑包装有限公司 Baoding Taizhou Paper Plastic Packaging Co. Ltd.				
生产方 Manufacture	—				
客户认定 样品信息 Submitted Sample Description	商标 Trade Mark:	—			
	样品名称 Sample Name:	一次性隔离衣, Single-use isolation gown			
	色号 Color:	—			
	数量 Quantity:	1,	描述 Description:	蓝色非织造物 Blue non-woven fabric	
	产品等级 Sample Grade:	—, 安全类别 Safety Category: —			
	声明款号 Style No.:	—			
检验类型 Test Type	委托检验 Requested Examination	来样日期 Date Received	2020-05-03	签发时间 Date Issued	2020-05-06



批准 Approved by

Wang Baojun (Director)



委托检验仅对来样负责, 不承担其他连带责任。This report is valid only for the samples delivered by clients.
对检验报告若有异议, 应于收到报告之日起 15 日内向检验单位提出, 逾期不再受理。If there is any objection concerning
the report, it is required that the objection should be put forth to the center within 15 days from the reception date of the
report.

备注
Notes

除非客户要求, 本报告检测结果及符合性判定不考虑测量结果的不确定度。Measurement uncertainty is not considered

	实测值 Results
抗渗水性能 (g) Impermeability to water(g) AATCC 42-2017	0.0
静水压(kPa) Hydrostatic pressure(kPa) AATCC 127-2017	20.3
以下空白 End of report	

Reusable Isolation Gown Level 2 Test Reports



Testing Report



Job No.: /


Report No.: HQ203051838-1

Date: June. 02, 2020

Applicant: Headwear Apparel Co.Ltd
South Of Xiaoyao Village, Ligezhuang Town, Jiaozhou, Qingdao,
Shandong Province, China ,266300

Manufacturers: /

Overall Rating:	
Data	<input type="checkbox"/>
Satisfactory	<input checked="" type="checkbox"/>
Unsatisfactory	<input type="checkbox"/>
Others, See Detail Enclosed	<input type="checkbox"/>

Sample Information		
	Client:	/
	ID:	/
	Brand:	/
	Item No.:	/
	Description:	Isolation Gown Level 2
	Fiber Content:	/
	Safety Category:	/
	Received Date:	May. 25, 2020
	Testing Period:	May. 25, 2020 to May. 28, 2020
	Testing Standard:	Selected tests as requested by applicants, details refer to following pages.
Service Location:	Hangzhou	
Remark:	This Report is the English Version of the Test Report No. HQ203051838.	

To be Continued

Authorized by:
HQTS QA International Services Co., Ltd.



Neil Peng
Supervisor



Test Summary:

No.	Test Items	Criterion	Test Summary
1	Water Resistance	GB/T 29511-2013 Level 3	Pass
2	Tear Strength	GB/T 29511-2013 Level 3	Pass
3	Tensile Strength	GB/T 29511-2013 Level 3	Pass
4	Seam Strength	GB/T 29511-2013 Level 3	Pass
5	Low Temperature Resistance	GB/T 29511-2013	Pass

*****To be Continued

Test Items	Test Standards	Criterion& Requirement	Test Result	Comments
Water Resistance	GB/T 4744-2013	GB/T 29511-2013 Level 3 Hydrostatic Pressure > 5.0kPa Decline Rate ≤ 50%	Before Abrasion: 42.1kPa After Abrasion : 36.0kPa Decline Rate: 14.5%	Pass
Tear Strength	GB/T 3917.3-2009	GB/T 29511-2013 Level 3 > 40N	MD: 44N CD: 40N	Pass
Tensile Strength	GB/T 3923.1-2013	GB/T 29511-2013 Level 3 > 100N	MD: 700N CD: 580N	Pass
Seam Strength	GB/T 13773.1-2008	GB/T 29511-2013 Level 3 > 75N	MD: 310N CD: 420N	Pass
Low Temperature Resistance	GB 24539-2009 Method 6.15 after pretreatment at -40 degree C for 8h	GB/T 29511-2013 Decline Rate ≤ 30%	MD: 690N CD: 580N Decline Rate of MD: 1.4% Decline Rate of CD: 0.0%	Pass

Remark:

- 1) Water Resistance: The rate of increase of water pressure was 80 ± 3 cm H₂O/min while the water pressure was applied below the test specimen and the water temperature is 20 ± 2 degree C. Abrasion Pretreatment Condition: Use Standard Wool Cloth, 9kPa Pressure, after 100 Times of Friction.
- 2) MD=Machine Direction; CD=Cross Direction
- 3) Low Temperature Resistance Test Items is out of lab's CMA, CNAS Certification.
- 4) All the Testing Requirements were Specified by Client.

*****End of Report

TEST REPORT

Reusable Level 2 Isolation Gown Wash Test Reports

Sample Description as Declared :

Sample Description : Level 2 Non-Surgical Isolation Gown
Color : Yellow
Style # : MS2160
Fabric/Garment Weight : 2.5 oz/yd²
Fiber Content : 100% Polyester
No. of Samples : 1
End Use : Non-Surgical Isolation Gown
Care Instructions : Machine Wash Cold, Wash Red And Dark Separately, Do Not Bleach, Remove Promptly, Tumble Dry Low, Touch Up With Cool Iron.
Sample Received Date : May 13, 2020
Final Confirmation Received Date : May 14, 2020
Report Completion Date : May 15, 2020



For and on behalf of
Intertek Products Group North America:

TEST RESULTS:

AATCC TM42-2017e: Water Resistance: Impact Penetration Test

Perform only in original state Performed over seams per ANSI AAMI PB70

Remark: Tested using Blotting Paper as specified in AAMI PB70 Standard.

Results are reported in grams of water absorbed. Sample does not have to be evaluated after wash per the method, but might be requested by the client. For values over 5 g, report as + 5.0 g or > 5.0 g.

Sample:	Level 1 Non-Surgical Isolation Gown (Headway)		
As Received	Specimen	Difference (gram)	Requirement
Critical Zone A	1	0	Data
	2	0	
	3	0	
	Average:	0	
Critical Zone B – Left Sleeve	1	0	Data
	2	---	
	3	---	
	Average:	0	
Critical Zone B – Left Sleeve Seam	1	0	Data
	2	---	
	3	---	
	Average:	0	
Critical Zone B – Right Sleeve	1	0	Data
	2	---	
	3	---	
	Average:	0	
Critical Zone B – Right Sleeve Seam	1	0	Data
	2	---	
	3	---	
	Average:	0	
Critical Zone C – Left Side		0	Data
		0	
		0	
	Average:	0	
Critical Zone C – Right Side	1	0	Data
	2	0	
	3	0	
	Average:	0	

The test results stated in this report relate only to the item(s) tested. This test report may not be reproduced except in full, without written approval of Intertek.

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If you need assistance in interpreting these results or if you have any questions, please feel free to call Customer Service Department

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