



Level 3 Disposable Isolation PP Gown

Last Update: July 29, 2020

Level 3 Disposable Isolation PP Gown



Level 3 Disposable Isolation PP Gown - Product Specs

MATERIAL	Polypropylene with polyethylene coating (PP/PE)
WEIGHT	35gsm
AAMI CLASS/LEVEL	Level 3, Non-Woven, Splash Resistant
STYLE	Long Sleeve, White Knitted Cuff, Neck Tie, Waist Tie
STERILIZATION	Non-Sterile
COLOR	Blue

SHUCHENG JIANGYAN GARMENT FACTORY
MAHEKOU STREET, CHENGGUAN TOWN, SHUCHENG COUNTY, LU'AN CITY, ANHUI PROVINCE, CHINA

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

Sample Description : (A)35g PP+PE Non Woven Fabric

Sample Color : (A)blue

Proposed Care Instruction : -

Sample Receiving Date : Jun 19, 2020

Testing Period : Jun 22, 2020 - Jun 28, 2020

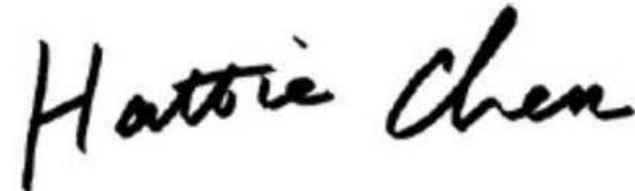
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant

Conclusion	A	Remark
Water Resistance(Hydrostatic Head)	PASS	
Water Resistance(Impact Penetration Test)	PASS	

Remark(s) : PASS=Meet Client's Requirement

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



Hattie Chen (Account Executive)

LLC

Test Result

Water Resistance(Hydrostatic Head)

(AATCC TM 127-2018;Hydrostatic Head; Rate of increase of water pressure: 60 mbar/min, temp. of distilled water: 21 °C, Face Side Facing Water)

(A)

<u>As Received</u>	No. 1	No. 2	No. 3	Average	Requirement
Water Column(cmH ₂ O)	>51.0	>52.0	>51.0	>51.0	>50cm

Water Resistance(Impact Penetration Test)

(AATCC TM 42-2017;Impact Penetration Type I Tester —Tested under controlled condition, water temperature : 27±1 °C)

(A)

<u>As Received</u>	No. 1	No. 2	No. 3	Average	Requirement
The weight of the blotter gained(g)	0.0	0.0	0.0	0.0	<1g

Sample Photo



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.



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

Shucheng Jiangyan Garment Co., Ltd

Mahekou Street, Chengguan Town, Shucheng County, Lu'an City, Anhui, China

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

Owner/Operator Number: 10072491



Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D398119	OEA	Non-surgical isolation gown	Non-surgical isolation gown
		Non-medical Isolation gown	Non-sedical Isolation gown

AH 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. AH 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. AH 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, AH is not affiliated with the U.S. Food and Drug Administration.

Ningbo AH Testing Services CO.,LTD.

W: www.fda.gov www.nb-ah.com

Tel: +86-574-86263152


 Executive Director Issued: Apr.23, 2020