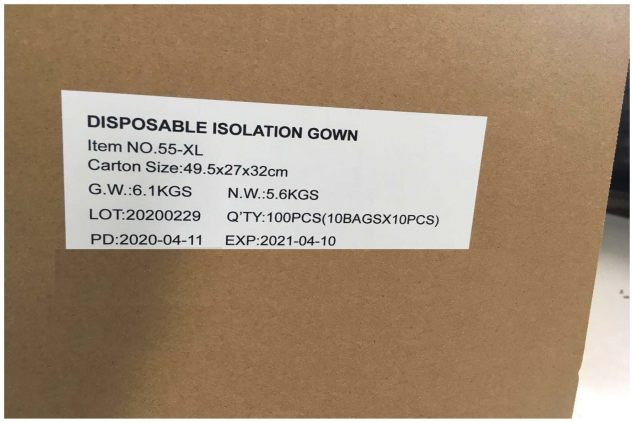
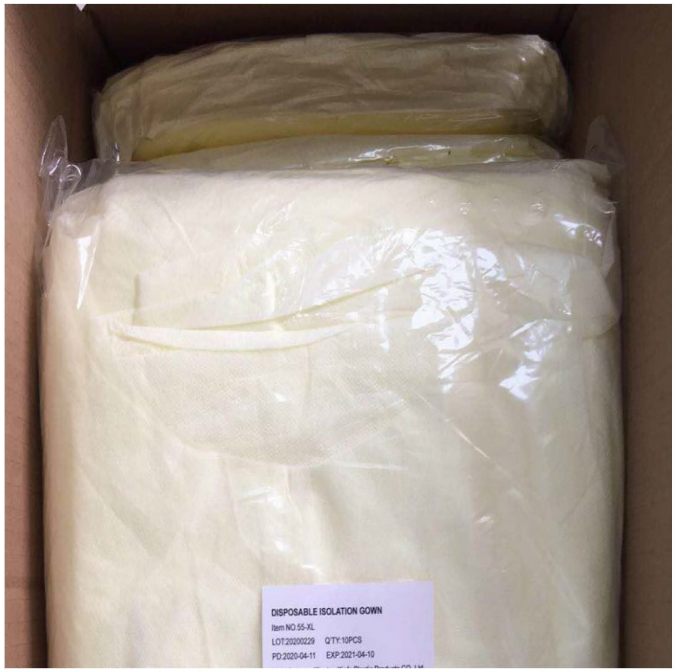
Isolation gown details：

Package:


DISPOSABLE ISOLATION GOWN
Item NO.55-XL
Carton Size:49.5x27x32cm
G.W.:6.1KGS N.W.:5.6KGS
LOT:20200229 Q'TY:100PCS(10BAGSX10PCS)
PD:2020-04-11 EXP:2021-04-10


Certificate of Compliance


DISPOSABLE ISOLATION GOWN
Item NO.55-XL
LOT:20200229 QTY:10PCS
PD:2020-04-11 EXP:2021-04-10


DISPOSABLE ISOLATION GOWN

TEST REPORT

Technical Report: (6620)112-0678

TEST REPORT

LAB NO.:	(6620)112-0678
FORM NO.:	/
DATE IN:	Apr 21, 2020
MODIFIED DATE IN:	Apr 24, 2020
DATE OUT:	Apr 27, 2020
NO. OF WORKING DAYS:	2
PAGE 2 OF 4	

OVERALL RATING	
PASS	
FAIL	
DATA	X

Vendor:		Agent:	/
Fabric Supplier/Mill:	/	Factory/Manufacturer:	
P.O. No.:	/	Style No.:	/
Sample Description:	ISOLATION GOWN	Style Description:	/
Color:	YELLOW	Country of Origin:	/
Claimed Fabric Weight:	/	Claimed Fabric Count:	/
Yarn Size:	/	Submitted Size:	/
Size Range:	/	FPU No.:	/
GPU No.:	/	End Use:	/
SKU:	/		

Product Category	/
Test Requested	PARTIAL TEST
Previous Report No.	/

Submitted Fiber Content	/
Actual Fiber Content	/
Suggested Fiber Content	/
Submitted Care Instruction(s)	/
Client Expected Care Instruction	/
Suggested Care Instruction(s)	/

C/N SM-CARD/AMY

TEST RESULTS

TEST PROPERTY — REQUIREMENTS

WATER RESISTANCE: HYDROSTATIC PRESSURE TEST (AATCC 127, METHOD A, OPTION 2, HYDROSTATIC HEAD TESTER AT 60 MBAR/MIN, DISTILLED OR DEIONIZED WATER AT 21 ± 2°C, 3 WATER DROPLETS)
(Note: 1mBar=1.02CMH_2O)

	SHELL	SLEEVE	SHOULDER	ARM OPENING @SIDE	BELT
Mbar					
1	433	378	443	339	208

WATER RESISTANCE: IMPACT PENETRATION TEST (AATCC 42)

INCREASED MASS (GRAM)	Main Body:	0.9	MAX./ GRAM
INCREASED MASS (GRAM)	sleeve seam:	0.5	MAX./ GRAM
INCREASED MASS (GRAM)	shoulder seam:	0.2	MAX./ GRAM
INCREASED MASS (GRAM)	armpit:	0.2	MAX./ GRAM
INCREASED MASS (GRAM)	belt:	0.9	MAX./ GRAM

END OF REPORT

CERTIFICATE OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate No.UKZB18MD20065R0M

Unified social credit code:91429004730841389M

This is to Certify that the Medical Device Quality Management System of

is in conformity with

YY/T0287-2017/ISO13485:2016 Standard applies to

DESIGN, PRODUCTION AND SALE OF NON-WOVEN PRODUCTS FOR MEDICAL APPLICATIONS
(ONLY EXPORT, THE PRODUCTS PROVIDED IN NO-STERILELY)

REGISTERED ADDRESS:SO

OPERATION ADDRESS:ZHONGLING INDU

H NCE, P.R.C.

Date of Initial Issuance: Jan. 15, 2016

Date of Re-Certification: Dec. 26, 2018

Date of Expiration: Jan. 14, 2022

BCC Inc.

President: 尚志强

BCC Address: Room 1101, Floor 11, Building 1, Guoyingyuan, Xicheng District, Beijing, P.R.C.
This certificate is valid within state - specified validities of administrative and qualification licensing.
The effectiveness of this certificate shall be maintained by regular surveillance audit,
the validity of the certificate can be inquired through www.bcc.com.cn or by QR code.
The information of this certificate available for inquiry on CNCA's website: www.cnca.gov.cn.
Accreditation by UKAS is granted to BCC for providing audits and certifications of ISO9001/ISO13485

8631

2020

CERTIFICATE OF REGISTRATION

This certifies that:

[redacted]

Pengcheng Town

[redacted]

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3006538071**
DUNS No.:	**53-114-9540**
Device Classification Name:	**NON-SURGICAL ISOLATION GOWN**
Product Code:	**OEA**
Regulation Number:	**878.4040**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp 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. Registrar Corp 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. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

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David Lennarz
Executive Director
Registrar Corp
Dated: November 12, 2019