



Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

**XIANTAO YUTIAN PROTECTIVE PRODUCTS CO.,LTD
NO. 3 ,XILIUHE STREET , XILIUHE TOWN XIANTAO, Hubei, 433000, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10064181

Listing No.	Product Code:	Device Name:
D378447	LYU	ACCESSORY, SURGICAL APPAREL - face mask, shoe cover, bed cover, cap
D378448	OEA	Non-surgical isolation gown -Protective Cloth

UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.



UCL-REGSERVICE INC.
602 ROCKWOOD ROAD, WILMINGTON,
NEW CASTLE DE 19802 USA

and on behalf of
UCL-REG SERVICE INC.

Authorized Signature(s)

Cert. No.: M20658
Issued Date: 24 March 2020
Expiration Date: 31 December 2020

Compliance Report

Applicant: Hubei Yutian Protective Products Co., LTD
Address: Group 2, Lion Rock Village, Mengusi Town, Fang County,
shiyan, Hubei, China

Product: Face mask, Cap, Hair net, Shoe cover, Surgical gown, Isolation
gown, Lab coat, Patient gown, Suit, Visitor gown, Apron,
Kimono, Raincoat, Boot, Beard cover, Sleeve cover, Glove,
Underwear, Bed cover, Bed sheet, Slipper, Bra, Coverall,
Pillow cover, Bathrobe, Ear shield, Scrub suit, Boot cover

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 03045

Initial Issue Date: 8 Mar 2019



Tony Chen

General Manager (Signature)



Annex to Report (No. 03045)

Hubei Yutian Protective Products Co., LTD

Product Name	Type
Face mask	17.5*9.5cm
Cap	18", 19", 21", 24"
Hair net	18", 19", 21", 24"
Shoe cover	15*39cm, 16*40cm, 17*41cm
Surgical gown	115*137cm, 120*140cm, 125*145cm
Isolation gown	115*137cm, 120*140cm, 125*145cm
Lab coat	82*140cm, 115*130cm, 120*140cm
Patient gown	115*137cm, 120*140cm
Suit	S-3XL
Visitor gown	115*130cm, 120*140cm
Apron	27"*42", 31*50"
Kimono	S-3XL
Rain coat	115*130cm, 120*140cm
Boot	S-3XL
Beard cover	18", 21"
Sleeve cover	20*40cm
Glove	S-3XL
Underwear	S-2XL
Bed cover	80*200cm, 140*240cm
Bed sheet	115*130cm, 120*140cm
Slipper	S-3XL
Bra	S-2XL
Coverall	S-3XL
Pillow cover	75*50cm, 45*45+10cm
Bathrobe	S-2XL
Earshield	S-2XL
Scrub suit	S-3XL
Boot cover	15*39cm, 16*40cm, 17*41cm

Note: Special specifications according to customer requirements.
This annex is only valid if attached to the report mentioned above.