



Home

Food

Drugs

Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Animal & Veterinary

Cosmetics

Tobacco Products

Establishment Registration & Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)



1 result found for **Establishment Registration**
or **FEI Number** : 3017952343

[New Search](#)

Establishment Name	Registration Number	Current Registration Yr
WUHAN YOUFU INTERNATIONAL TRADE CO.,LTD CHINA	3017952343	2022
Face Mask Per Enforcement Policy For Face Masks And Respirators During The Declared Public Health Emergency - Disposable Face Mask, Disposable Beard Cover, Face Mask With Shield, Paper Mask, Face Shield, Dust Mask		Foreign Exporter
Non-Surgical Isolation Gown - Lab Coat, Isolation Gown, Coverall, Scrub Suits, CPE Gown, Patient Gown, Disposable Pants		Foreign Exporter
Bedding, Disposable, Medical - Disposable Bed Sheet, Disposable Bed Cover, Pillow Case, Under Pad, Transfer Sheet, Nonwoven Bags		Foreign Exporter
Cap, Surgical - Disposable Cap, Disposable Hoods		Foreign Exporter
Accessory, Surgical Apparel - Sleeve Cover		Foreign Exporter
Apron, Protective - Apron, Raincoat		Foreign Exporter
Cover, Shoe, Operating-Room - Shoe Cover, Boot Cover		Foreign Exporter



This is to certify that the Quality Management System of

Wuhan Youfu International Trade Co., Ltd.

Unified Social Credit Code: 91420111MA49J1A889

Operation Address: Room 3, 18/F, Unit B, Building S-1, Kaile Guiyuan, No.108, Zhuodaoquan Road, Hongshan District, Wuhan City, Hubei Province, China

Registered Address: Room 3, 18/F, Unit B, Building S-1, Kaile Guiyuan, No.108, Zhuodaoquan Road, Hongshan District, Wuhan City, Hubei Province, China

applicable to

Sales of disposable non-sterile hygiene medical protective products(face masks, isolation gowns, coveralls, scrub suits, bed sheets, bed cover, pillow cases, lab coats, caps, sleeves cover)(export to Thailand, South Korea, Australia and Costa Rica)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number

129996

Date:

13 July 2021

Valid Until:

13 July 2024



0015



DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Wuhan Youfu International Trade Co., Ltd.

Room 3, 18F, unit B, Building S-1, Kaile Guiyuan,
No.108, Zhuodaoquan Road, Hongshan District,
Wuhan City, Hubei Province, China

Trademark:

SRN:

NL-AR-000000121

European Representative:

Lotus NL B.V
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.
Medicines and Healthcare Products Regulatory Agency
Competent Authority NL (CIBG)

SRN:

Not available yet

Trade name:

Isolation gown (non-sterile)

Product Name:

Isolation gown (non-sterile)

Product code / Catalogue number:

YF- IG

Basic UDI:

Not available yet

Classification acc. to MDR Ax. VIII:

Class I, rule I

Applied Standard & Common Specification:

EN 13688:2013 EN ISO 14971:2012 EN 1041:2013
EN ISO 15223-1:2016 EN ISO 10993-10:2013
EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

Name and ID of the Notified Body:

N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), and the provision of the Regulation (EU) 2016/425 on personal protective equipment. All supporting documentations are retained under the premises of the manufacturer.

Signature:

General Manager



Wuhan, 22.11.2020