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### **Establishment Registration & Device Listing**

FDA Home Medical Devices Databases





1 result found for Establishment Registration

or FEI Number: 3017952343

New Search

Establishment A	Registration Number	Current Registration Yr
WUHAN YOUFU INTERNATIONAL TRADE CHINA CO.,LTD	3017952343	2022
<ul> <li>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</li> </ul>		Foreign Exporter
<ul> <li>Non-Surgical Isolation Gown - Lab Coat, Isolation Gown, Coverall, Scrub Suits, CPE Gown, Patient Gown, Disposable Pants</li> </ul>		Foreign Exporter
<ul> <li>Bedding, Disposable, Medical - Disposable Bed Sheet, Disposable Bed Cover, Pillow Case, Under Pad, Transfer Sheet, Nonwoven Bags</li> </ul>		Foreign Exporter
<u>Cap, Surgical - Disposable Cap, Disposable Hoods</u>		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 NOA.

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.snga.com.cn

Managing Director

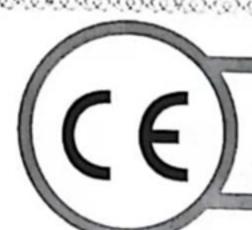
Certificate Number

129996



Date: Valid Until: 13 July 2021 13 July 2024





# **DECLARATION OF CONFORMITY**

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

## **Conformity Assessment**

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971: 2019 EN ISO 15223-1: 2016 EN ISO 20417:2021 ISO 10993-1: 2018 EN ISO 10993-5: 2009 EN ISO 10993-10: 2013

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-BBS-03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

### Manufacturer

Name: Wuhan Youfu International Trade Co., Ltd Address: Room 3, 18F, unit B, Building S-1, Kaile Guiyuan, No. 108, Zhuodaoquan Road, Hongshan District, Wuhan City, Hubei Province, China

### **Product Information**

Name: DISPOSABLE BED SHEET

Model: YF7001,7002,7003,7004,7005,7006,7007

GMDN: 47456 Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex

VIII, Regulation (EU) 2017/745

### Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

