



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
<a href="#">WUHAN YOUFU INTERNATIONAL TRADE CO.,LTD</a> CHINA	3017952343	2022
<ul style="list-style-type: none"><li><a href="#">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</a></li></ul>		Foreign Exporter
<ul style="list-style-type: none"><li><a href="#">Non-Surgical Isolation Gown - Lab Coat, Isolation Gown, Coverall, Scrub Suits, CPE Gown, Patient Gown, Disposable Pants</a></li></ul>		Foreign Exporter
<ul style="list-style-type: none"><li><a href="#">Bedding, Disposable, Medical - Disposable Bed Sheet, Disposable Bed Cover, Pillow Case, Under Pad, Transfer Sheet, Nonwoven Bags</a></li></ul>		Foreign Exporter
<ul style="list-style-type: none"><li><a href="#">Cap, Surgical - Disposable Cap, Disposable Hoods</a></li></ul>		Foreign Exporter
<ul style="list-style-type: none"><li><a href="#">Accessory, Surgical Apparel - Sleeve Cover</a></li></ul>		Foreign Exporter
<ul style="list-style-type: none"><li><a href="#">Apron, Protective - Apron, Raincoat</a></li></ul>		Foreign Exporter
<ul style="list-style-type: none"><li><a href="#">Cover, Shoe, Operating-Room - Shoe Cover, Boot Cover</a></li></ul>		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](http://www.cnca.gov.cn))

SNQA's website: [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number

**129996**

Date:

13 July 2021

Valid Until:

13 July 2024



0015







# 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.

Signature:  Date: 2021-09-09

Position: GM Place: Wuhan/China