



# 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  
EN ISO 10993-1:2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 14126:2003

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-VHC-01.*

*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 medical protective coverall

**Model:** YF5003

**GMDN:** 58390

**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: *Erina* Date: 2021-09-09

Position: GM

Place: Wuhan/China

