



# 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: 2021  
EN 1041:2008+A1:2013  
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-YZ-04.*

*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:** Hubei Yazhi Hygiene Products Co., Ltd  
**Address:** South side of Shahu Avenue, Shahu Town, Xiantao City, Hubei Province, China,433000  
**SRN:** CN-MF-000010782

## Product Information

**Name:** Disposable Gown  
**Model:** 05561-Y, 05561-Y-XXL  
**GMDN:** 58390  
**Basic UDI-DI:** 697480528DisposableGownNP  
**Classification:** Class I

## 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: 2022-10-17

Position: General Manager

Place: Xiantao / China



周慢玉