



# 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 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-AS-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:** Yangzhou Super Union Import & Export Co., Ltd.

**Address:** No.120 Xishan South Road Chenji Town  
211408 Yizheng City, Yangzhou City, Jiangsu Province CHINA

**SRN:** CN-MF-000010954

## Product Information

**Name:** Alcohol swab

**Model :** 3\*6CM, 3\*6.5CM, 5\*5CM, As per customer requirements

**GMDN:** 13913

**Basic UDI-DI:** 6974265590001746

**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: 10<sup>th</sup> September, 2021

Position: GM

