



# 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-00000247**

## 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  
EN ISO13485:2016

### Remark

*The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF002.*

*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: WUXI WEMADE HEALTHCARE PRODUCTS CO., LTD.  
Address: NO.1060, Antai 3 Road An Town, Xishan District, Wuxi 214105 China.

## Product Information

Name: Tape

Model: -

Basic UDI-DI: Sports Tape

3.8cm*10m	69387992ST0042Z
3.8cm*13.7m	69387992ST0012T
2.5cm*9.1m	69387992ST0022V
3.8cm*9.1m	69387992ST0032X
3.75cm*10m	69387992ST00533

**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:2021.12.11

Position: GM  Place: China