



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