



EC Declaration of Conformity



Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:

Name: WuXi WeMade Healthcare Products Co., Ltd.

Address: NO. 1060, Antai Three Road, An Town Xishan District, Wuxi City, Jiangsu Province.
CHINA

European Authorized Representative :

Name: SUNGO Europe B.v

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

Product:

Name: Sports Tape

Model: -

Classification: I

Rule: According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU)2017/745.

Conformity Assessment Route:

Annex II&III in Medical Device Regulation (EU 2017/745)

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 13485:2016/EN ISO 14971:2012

EN ISO 15223-1:2016 / EN 1041:2008

ISO 10993-1:2018 / EN ISO 10993-5:2009 / EN ISO 10993-10:2013

Signature:



Date: January 20, 2020

Position: General Manager