



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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 ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-M03030199-01.*

*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: Hubei Junyan Medical Science &
Technology Co.,Ltd
Address: No.6, Yingling Road, Railway Station
Development Zone, Huangzhou District,
Huanggang, Hubei, China.
SRN: CN-MF-000045028

Product Information

Name: Silicone Tape
Model: 2cm*3M, 4cm*1.5M, 2.5cm*0.75M,
2.5cm*1.5M, 7.5cm*1.5M, 10cm*20cm, 10cm*30cm,
10cm*40cm, 16cm*16cm, 16cm*21cm, 16cm*21cm,
16cm*31cm, 21cm*21cm, 26cm*26cm,
customization
EMDN: M03030199
Basic UDI-DI: 697084909STEU01Y9
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: 2024.11.12

Position: GM

Place: Hubei /China