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-TNQ-02.

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: TNQ INDUSTRIAL CO., LTD
Address: 301, No.20, Aimin Road, NanCun Town, Panyu District, Guangzhou City, Guangdong P.R., China

Product Information

Name: TOURNIQUET
Model: TNQ-T0A00, T0B00, TNQ-T0C00, TNQ-T0D00, TNQ-T0K00, TNQ-YP00, TNQ-T0E00, TNQ-T0E01, TNQ-T0E02, TNQ-T0E03, TNQ-T0F00,TNQ-TDT00, TNQ-TDT01, TNQ-TDT02, TNQ-TDT03
GMDN: 58128
Basic UDI-DI: /
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: 2021.6.3

Position: GM Place: Guangdong/China