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

Manufacturer

Name: Guangzhou Tourniqueen Medical Instrument' s Co., Ltd.
Address: 1F&2F, Building B, Aigang Industrial Park, Yuexi Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, China

Product Information

Name: Tourniquet
GMDN: 58128
Basic UDI-DI:
697311851TN-001BW
697311851TN-003C2
697311851TN-004C4
697311851TN-005C6
697311851TN-006C8
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

SRN:CN-MF-000009013

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF001.

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.

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: 2021.7.17

Position: GM Place: Guangdong/China

Name: Zhang Xiuxiu