



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: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
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-C90010301-01.

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: SHENZHEN ZHONGDA HOOK&LOOP CO.,LTD
Address: NO.20, LUOWU STREET, LIULIAN COMMUNITY, PINGDI TOWN, LONGGANG DIST, SHENZHEN CITY, GUANGDONG, CHINA
SRN:

Product Information

Name: Tourniquet
Model: ZD2206100769
GMDN: 58128
EMDN: C90010301
Basic UDI-DI: /
Classification: Class I

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: 2022.6.13

Position: GM

Place: Shenzhen/China

