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-C90010301-02.

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: Dragon Medical Co.,Ltd
Address:Room B2313-B2314, 13 block of Injoy Plaza, Yangshe Town, Zhangjiagang City, Jiangsu Province, China
SRN:CN-MF-000011438

Product Information

Name:Tourniquet
Model:DW-FA015、DW-FA015A、DW-FA017、DW-FA018、DW-FA019
GMDN: 58128
EMDN: C90010301
Basic UDI-DI: 697467901DWTOUVT
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: 2022.4.21

Position: GM Place: Zhangjiagang/China