



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
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 1041: 2008
EN 1789: 2007

Remark

The declaration of conformity is valid in connection with the release technical document DHD-MDR. 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: XIAMEN DAHTON MEDITECH CO., LTD.
Address: Area A, Factory 1/F, No.99,Hu Li Industry Zone, MeiXi Road, Tong An District, Xiamen, the People's Republic of China

Product Information

Name: Cervical Collar
Model: Mini
GMDN: 45129
Basic UDI-DI: 6974262002020401FF
Classification: Class I
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: *Dahwa Lin* Date:2021-04-08

Position: General Manager Place: Xiamen/China