



# 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: Adult  
GMDN: 45129  
Basic UDI-DI: 6974262002010401F4  
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