



Declaration of Conformity



Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: ZHANGJIAGANG XIEHE MEDICAL APPARATUS&INSTRUMENTS CO.,LTD.
Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town,
Zhangjiagang City, Jiangsu 215600, China

European Authorised Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Cervical Collar
Model: - XH-17 XH-19 Philadelphia Collar

SRN: -

UDI-DI: -

Classification: I

Rule: According to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Medical Device Regulation (EU) 2017/745) and the following harmonized standards.

EN ISO 14971: 2012

EN ISO 15223-1: 2016

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN 1041: 2008

EN 62366-1:2015



Signature:

Authorized Signature (S)

Position: General manager

Date: 2020.6.29