DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The 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
EN 62366-1: 2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-XH06-01.

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: ZHANGJIAGANG XIEHE MEDICAL APPARATUS & INSTRUMENTS CO,.LTD.
Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China
SRN:CN-MF-000008449

Product Information

Name: Splint
Model: YXH-9A YXH-9B XH-15A XH-15B YXH-9 YXH-10 YXH-8B
GMDN: 43565&43588
Basic UDI-DI: 6974580870003DS
Classification: Class I, According to 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: Date: 2021.9.

Position: G.M. Place: Zhangjiagang

Intended Use

Splints are provided to people who need protection and support for painful, swollen or weak joints and their surrounding structures. Their designs make sure you position your Limbs (E.g. arm, finger, leg) correctly. It also provides support and stabilizer to the Limbs.