# 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.*

Digitally signed by Alexa Gheorghe
Date: 2026.05.29 12:59:19 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

## Manufacturer

**Name:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND 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: 2021.9.17

Position: G.M. Place: Zhangjiagang.