



# 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  
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-XH01-01.*

*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 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:** Emergency Stretcher & Stretcher Accessories  
**Model:** see Annex  
**GMDN:** 35892  
**Basic UDI-DI:** 6974580870001DN  
**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

# Annex

## Emergency Stretcher

YXH-1A1	YXH-1L	YXH-2T2	YXH-4D	YXH-6D
YXH-1A2	YXH-1M	YXH-3A	YXH-5A	YXH-C1
YXH-1A3	YXH-1K	YXH-3A2	YXH-5B	YXH-C2
YXH-1A5	YXH-1N(A)	YXH-3A3	YXH-5C	YXH-2R2
YXH-1A6	YXH-1N(B)	YXH-3A5	YXH-5D	XH-4C
YXH-1B1	YXH-1N(C)	YXH-3B	YXH-5E	XH-5C
YXH-1B2	YXH-A2	YXH-3B2	YXH-5F	ATHENA I
YXH-1B3	YXH-1A6L	YXH-3B3	YXH-5K	ATHENA II
YXH-1C	YXH-1A6A	YXH-3C	YXH-5N	ATHENA III
YXH-1D	YXH-1A6B	YXH-3D	YXH-5G	VENUS I
YXH-1DL	YXH-1A6C	YXH-3D2	YXH-5H	VENUS II
YXH-1E	YXH-1A6D	YXH-3E	YXH-5L	VENUS III
YXH-1EF	YXH-1A6E	YXH-3E2	YXH-5M	VENUS IV
YXH-1EL	YXH-1A6G	YXH-3E3	YXH-5O	NEPTUNE
YXH-1F1	YXH-1A6H	YXH-3F	YXH-5P	HESTIA
YXH-1F1B	YXH-1A6K	YXH-3G	YXH-C3	HESTIA I
YXH-1F2	YXH-1A6M	YXH-2L2	YXH-C4	HERMES I
YXH-1F3	YXH-1A6N	YXH-3K	YXH-6A	HEPHAESTUS II
YXH-1F4	YXH-4E	YXH-3H	YXH-6B	HESTIA III-B
YXH-1F4A	YXH-1A6A-2	YXH-7N	YXH-6C	HERMES II
YXH-1G	YXH-2A	YXH-4A	One-piece Basket Stretcher	
YXH-1GL	YXH-2B	YXH-4B	Two-piece Basket Stretcher	
YXH-1H	YXH-2C	YXH-4C	HEPHAESTUS III	YXH-5L-1
EC1	EC2	YXH-7A	YXH-7B	YXH-7C

## Emergency Accessories

Safety Belts	Spider Straps	S01	S02	XH-509
XH-510	XH-511	XH-512	2 HOOKS IV POLE	
4 HOOKS IV POLE				

