



### 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: Emergency Stretcher & Stretcher Accessories  
Model: - see annex

SRN: -

UDI-DI: -

*On behalf of SUNGO Europe office, I confirm  
EU REP of the company who issue this document*



*Authorized Signatory*

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: *[Handwritten Signature]*

Position: *[Handwritten Signature]* General manager

Date: *2020.6.29*

## 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	
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				

*On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.*



*[Handwritten Signature]*

Authorized Signature (S)



*Confirmed we are  
document.*

*[Handwritten Signature]*  
Signature (S)