



# 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: 2023  
EN ISO 10993-23: 2021

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-V08050101-01.*

*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:** Emergency Stretcher & Stretcher Accessories  
**Model:** See Annex  
**EMDN:** V08050101  
**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: 2024.11.22

Chu Weiming

Position: General Manager Place: Zhangjiagang/China



## Intended Use:

It is used to help the transportation of the injured people and for the rescue, immobilization and transport of the wounded.

## Annex

### Model

YXH-1A1, YXH-1A2, YXH-1A3, YXH-1A5, YXH-1A6, YXH-1B1, YXH-1B2, YXH-1B3, YXH-1C, YXH-1D, YXH-1DL, YXH-1E, YXH-1EF, YXH-1EL, YXH-1F1, YXH-1F1B, YXH-1F2, YXH-1F3, YXH-1F4, YXH-1F4A, YXH-1G, YXH-1GL, YXH-1K, YXH-1H, YXH-1L, YXH-1M, YXH-1N(A), YXH-1N(B), YXH-1N(C), YXH-1A6L, YXH-7N, YXH-2A, YXH-2B, YXH-2T2, YXH-2L2, YXH-4E, YXH-8A, YXH-3A, YXH-3A2, YXH-3A3, YXH-3A5, YXH-3B, YXH-3B2, YXH-3B3, YXH-3C, YXH-3D, YXH-3D2, YXH-3E, YXH-3E2, YXH-3E3, YXH-3H, YXH-3K, YXH-C1, YXH-C2, YXH-3F, YXH-3G, YXH-3K, YXH-3GW, YXH-4A, YXH-4B, YXH-4C, YXH-4D, YXH-4F, YXH-1A6A, YXH-1A6A-2, YXH-1A6C, YXH-1A6D, YXH-1A6E, YXH-1A6F, YXH-1A6G, YXH-1A6K, YXH-1A6B, YXH-1A6M, YXH-1A6J, YXH-1A6P, YXH-1A6N, YXH-1A6H, YXH-1A6O, YXH-1A6R, YXH-1A6T, YXH-6A, YXH-6B, YXH-6C, YXH-6D, YXH-5A, YXH-5B, YXH-5C, YXH-5D, YXH-5E, YXH-5G, YXH-5N, YXH-5K, YXH-5H, YXH-5L, YXH-5M, YXH-5O, YXH-5P, YXH-C3, YXH-C4, YXH-A2, YXH-5L-1, YXH-5M2, YXH-5F, YXH-5L-2, EC1, EC2, EC3, YXH-8A, YXH-4E, YXH-7A, YXH-7B(A), YXH-7B(B), YXH-7C, XH-509, XH-510, XH-511, XH-512, YXH-1F4B, XH-1F4B, YXH-1F4C, YXH-1F4D, YXH-1F4E, YXH-2L, YXH-3L ATHENA I, ATHENA II, ATHENA III, ATHENA IV, ATHENA V, VENUS I, VENUS II, VENUS III, VENUS IV, VENUS V, NEPTUNE, HESTIA I, HESTIA II, HESTIA III, HESTIA III-B, HESTIA IV, HESTIA V, HESTIA VI, HEPHAESTUS I, HEPHAESTUS II, HEPHAESTUS III, HERA I, HERA II, HERMES I, HERMES II, APOLLO I, APOLLO II, B4, B6, SPIDER STRAP, IV STAND, WALKER

