



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: 2024.01.22

Position: GM Place: Zhangjiagang/China



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, SAFETY BELT, SPIDER STRAP, IV STAND, WALKER