



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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-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.

Intended Use

Emergency Stretcher is used to help the transportation of the injured people.

Manufacturer

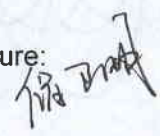
Name: ZHANGJIAGANG XIEHE MEDICAL APPARATUS & INSTRUMENTS CO.,LTD.
Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China
SRN:CN-MF-000008449

Product Information

Name: Emergency Stretcher & Stretcher Accessories
Model: see Annex
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	
EC1	EC2	YXH-7A	YXH-7B	YXH-7C

Emergency Accessories

Safety Belts B4 B6 Spider Straps

S01

S02

XH-510

XH-511

XH-512

2 HOOKS IV POLE

4 HOOKS IV POLE

XH-509

