



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN:

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation(EU)2017/745

Applicable Standards

EN ISO 14971:2019; ENISO 15223-1:2016
EN1041:2008+A1:2013; ISO 10993-1:2018
EN ISO 10993-5:2009; EN ISO 10993-10:2013
IEC 62366-1:2015;

Remark

The declaration of conformity is valid in connection with the release technical document <CE-MDR-TCF02- Medical stretcher>

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 HERUI MEDICAL EQUIPMENT CO.,LTD.

Address: No.40 BaiXiong Road,SanXing JinFeng Town,ZhangJiaGang City,JiangSu Province,China

Product Information

Name : Medical stretcher

Model : See Annex

GMDN : 35892

Basic UDI-DI : We will apply the UDI and have the UDI-DI placed on the label of devices before May 26, 2025 as per the requirement of Article 123, 3f) of Regulation (EU) 2017/745

Classification: According to the rule1, Annex VIII of Medical Device 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: *Tongde Xu* Date: *2021.1.29*

Position: *General Manager* Place: *Zhang Jia Gang*



Annex

Product Name	Model	GMDN	Basic UDI-DI
Medical stretcher	YHR-W1, YHR-W2, YHR-W3, YHR-W4, YHR-W5, YHR-W6 YHR-CS1, YHR-CS2, YHR-CS3, YHR-CS4 YHR-A1, YHR-A2, YHR-A3, YHR-A4, YHR-A5, YHR-A6, YHR-A7, YHR-A8, YHR-A9, YHR-A10, YHR-A11, YHR-L1, YHR-L2 YHR-S1, YHR-S2, YHR-S3, YHR-S4, YHR-S5, YHR-S6, YHR-S7, YHR-S8, YHR-S9, YHR-S10 YHR-Q1, YHR-Q2, YHR-Q3 YHR-B1, YHR-B2, YHR-B3, YHR-B4 YHR-1A1, YHR-1A2, YHR-1A3, YHR-1A4, YHR-1A5, YHR-1A6, YHR-1A7, YHR-1A8, YHR-1A9, YHR-1A10, YHR-1A11, YHR-1A12 YHR-1F1, YHR-1F2, YHR-1F3, YHR-1F4 YHR-E4A, YHR-E4B YHR-E1, YHR-E2 YHR-EVA, YHR-VM7D, YHR-N1, YHR-PT YHR-D1, YHR-D2, YHR-D3, YHR-D4 YHR-JT1, YHR-JT2, YHR-JT3, YHR-JT4 YHR-HD1, YHR-HD2 YHR-ED01, YHR-ED02 YHR-TG1, YHR-TG2 YHR-SS1, YHR-SS2	35892	We will apply the UDI and have the UDI-DI placed on the label of devices before May 26, 2025 as per the requirement of Article 123, 3f) of Regulation (EU) 2017/745

Signature: *Tongde Xu* Date: *2024.1.29*

Position: *General Manager* Place: *Zhong Jia Gang*

