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: 2021.1.29

Position: General Manager Place: Zhang Jia Gang

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