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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-RX-08.

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: JIANGSU RIXIN MEDICAL EQUIPMENT CO., LTD.
Address: No.427 Yangjin Road, Jinfeng, Zhangjiagang, Jiangsu Province, China
SRN:CN-MF-000008761

Product Information

Name: PE Stretcher
Model: YDC-7A1, YDC-7A3, YDC-7A4, YDC-7B1, YDC-7B2, YDC-7C1, YDC-7C2, YDC-7D1, YDC-7E, CB-01
EMDN: V08050103
Basic UDI-DI: 697444205711JV
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Intended use: PE stretcher is used for transport patients and wounded person with cervical and lumbar injuries. Fix the safety belts on the stretcher, and it can be used with head immobilize at the same time.

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: ZHOU JIAN PIN
Position: GM
Place: Jiangsu /China
Date:2023.11.30

JIANGSU RIXIN MEDICAL EQUIPMENT CO.,LTD 江苏日新医疗设备股份有限公司