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

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 Jianping
Position:GM

Date: 2023.11.20
Place: Jiangsu /China

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