



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-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.

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: Foldaway Stretcher

Model: YDC-1A1, YDC-1A3, YDC-1A4, YDC-1A4H,
YDC-1A5, YDC-1A6, YDC-1A7, YDC-1A9,
YDC-1A10, YDC-1A11, YDC-1A12, YDC-1A13,
YDC-1A14, YDC-1A16, YDC-1A17, YDC-1A19,
YDC-1A22, YDC-1A23, YDC-1F1, YDC-1F2,
YDC-1F3, CST-01, CST-05

EMDN: V08050101

Basic UDI-DI: 697444205111HX

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 Jian ping
Position: GM

Date: 2023.11.20

Place: Jiangsu, China

