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

Manufacturer

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

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019/A11:2021
ISO 15223-1: 2021/Amd 1:2025
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009/A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name: PE Stretcher
Model: YDC-7A1,YDC-7A3,YDC-7A4,YDC-7B1, YDC-7B2,YDC-7C1,YDC-7C2,YDC-7D1,YDC-7E, YDC-7F1, YDC-7F2, CB-01
EMDN: V080501
Basic UDI-DI: 697444205PS001G4
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: Date:2025/8/21

Position: GM Place:Jiangsu/China

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-005.

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.

File No.: MDR-TCF-005-08