



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-02.

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: Stair Stretcher
Model: YDC-5L, YDC-5L01, YDC-5L02, YDC-5G, YDC-5M, YDC-5T1, YDC-5T2, YDC-5P, YDC-5R
EMDN : V0805030101
Basic UDI-DI : 697444205511JK
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 Date: 2021.12.20

Position: GM Place: Jiangsu / China

