



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/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

Remark

*The declaration of conformity is valid in connection
with the release technical document
MDR-TCF-017.*

*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: Safety Belt
Model: B2,B4,B8,B9,B10,B11,B12
EMDN: Y122406
Basic UDI-DI: 697444205SB001DE
Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745
Intended purpose: Safety Belt is used for fix the
patient slips and falls from the stretcher.

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

Zhou Jianping

Position: GM

Place: Jiangsu/China