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-010.

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: Head Immobilize
Model: HD-01,HD-03
EMDN: M030599
Basic UDI-DI: 697444205HI001B6
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Intended purpose: Head Immobilize is used for fixing the patient's head.

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

File No.: MDR-TCF-010-08