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
EN ISO 10993-1

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-RX-03.

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： 697444205101HU
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: ZHOU JIAN PING
Position: GM
Place: Jiangsu /China
Date:2023.11.30

JIANGSU RIXIN MEDICAL EQUIPMENT CO.,LTD 江苏日新医疗设备股份有限公司