



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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

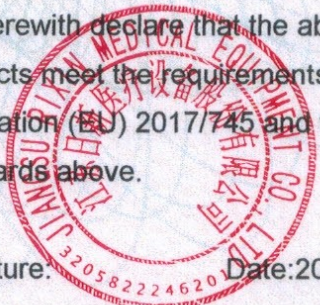
Name: JIANGSU RIXIN MEDICAL EQUIPMENT CO.,
LTD.
Address: No.427 Yangjin Road, Jinfeng,
Zhangjiagang, Jiangsu Province, China
SRN: CN-MF-000008761

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