DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert Gmbh
Harffstr. 47,40591 Düsseldorf, Germany
SRN: DE-AR-000010869

Manufacturer

Name: ZHANGJIAGANG MEDI MEDICAL EQUIPMENT CO., LTD
Address: Room 614 of Guotai New World Square, No.19 of Renmin East Road, Yangshe Town,Zhangjiagang City, Jiangsu Province
SRN: CN-MF-000036799

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: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name: MANUAL HOSPITAL BED
Model: YA-M5-6,YA-H5-1,YA-H5-3,YA-M5-5,YA-M5-1,YA-H3-1,YA-M3-1,YA-M3-2,YA-M3-3,YA-M3-4,YA-M2-3,YA-M2-5,YA-M2-6,YA-M2-7,YA-H2-1,YA-M1-1,YA-M1-3,YA-M1-4,YA-M0-1,YA-M0-2,YA-EC-W03,YA-EC-M01,YA-EC-M02,YA-EC-S02,YA-EC-M03,YA-EC-S04,YA-EC-W02,YA-PM3-1,YA-PM2-3,YA-PM1-1,MK-B03,MK-B04,MK-B07
EMDN: V080602
Basic UDI-DI: /
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: Date:2024.11.14

Position: GM Place: Zhangjiagang/China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080602-01.

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.