DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE

Amsterdam, Netherlands

SRN: NL-AR-000000247

Manufacturer

Name: HI-LIFE TECHNOLOGY (HEBEI) CO.,LTD

Address:67.2 KM OF THE SOUTH OF NO.112 HIGHWAY, BAZHOU, HEBEI PROVINCE, CHINA

SRN:

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: 2013

Product Information

Name: Hospital Bed

Model： HL-A120A 、 HL-A120B 、 HL-A120C 、 HL-A120D；HL-A131A、HL-A131B、HL-A131C、HL-A132A、HL-A132B、HL-A132C、HL-A133A、HL-A133B、HL-A133C、HL-A134A、HL-A134B、HL-A134C；HL-A141A、HL-A141B、HL-A141C、HL-A142A、HL-A142B、HL-A142C、HL-A143A、HL-A143B、HL-A143C；HL-A151A、HL-A151B、HL-A152A、HL-A152B、HL-A153A、HL-A153B

EMDN: V080602

GMDN: 34873

Basic UDI-DI: 697546136HBA13G6, 697546136HBA12G4, 697546136HBA14G8, 697546136HBA15GA

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

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.

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: 2022.04.19

Position: GM Place: Hebei/China