



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

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

EN 60601-2-52:2010/A1:2015

EN 60601-1:2006/ A2:2020

EN 60601-1-2:2015/A1:2020

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080601-01.

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.

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, China

SRN:

Product Information

Name: Electric Hospital Bed

Model : YA-D7-3, YA-D8-2, YA-D7-2, YA-D8-1, YA-D5-12, YA-D5-7, YA-PD5-1, YA-D5-11, YA-D5-13, YA-D5-1, YA-D6-1, YA-D5-3, YA-D5-4, YA-D5-5, YA-D3-1, YA-D3-3, YA-D5-9, YA-D3-4, YA-DH6-1, YA-DH5-3, YA-DH5-1, YA-DH5-2, YA-DH3-2, YA-ET-D01, YA-ET-H02

EMDN: V080601

Basic UDI-DI: /

Classification: Class I, According to Rule 13, 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: 2023/4/24

Position: GM

Place: Zhangjiagang/China