

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: 2023
EN ISO 10993-23: 2021
EN 60601-1-2:2015/A1:2021
EN 60601-1:2006/A2:2021
EN 12184: 2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.

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

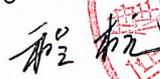
Name: ZheJiang J&J Mobility Co., Ltd
Address: #18, Baiyang Street, WuyiJinhua City, ZheJiang. China
SRN: CN-MF-000035084

Product Information

Name: Power Wheelchair
Model: JJW-6001, JJW-6001A, JJW-6002, JJW-6003, JJW-6003A, JJW-6004, JJW-6005, JJW-5001, JJW-5002, JJW-5003, JJW-5004, JJW-5005, JJ-W521, JJ-W5216, JJ-EA8000, JJ-EA8000S, JJW-7001, JJW-7002, JJW-7003, JJW-7004, JJW-7005
EMDN: Y122127
Basic UDI-DI: 697624501JJW001H6
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: 2023.8.30

Position: GM  Place: Zhejiang/China