DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 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
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 12184:2014
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021
EN 62366-1:2015

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 Richall Medical Technology Co., Ltd
Address: No. 353 Baozhang Avenue, Xianhua Street, Pujiang County, Jinhua City, Zhejiang Province
SRN: CN-MF-000038994

Product Information

Name: POWER WHEELCHAIR
Model: N3901,N3901A,N3901B,N3901C,W3902,W3902A,W3902B,W3902C,W3501,W3501A,W3501B,W3501C,N3502,N3502A,N3502B,N3502C
EMDN: Y122127
Basic UDI-DI: 697676662PW01V4
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:2023/8/31

Position: GM Place: Jinhua/China