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 Zhonglei Medical Technology Co.Ltd
Address: 1st floor, 2nd floor, No. 66, Dayuan Street, Nanmingshan Street, Liandu District, Lishui City, Zhejiang Province, China.
SRN: CN-MF-000039322

Product Information

Name: POWER WHEELCHAIR
Model:
N6101, N6101A, N6102, N6103, N6103A, N6105, N6105A, N6106, N6106A, N6107, N6108, N6109, N6201, N6201A, N6201B, W6202, W6202A, W6202B, W6203, W6203A, W6203B. W6205
EMDN: Y122127
Basic UDI-DI: 697710078PW01ME
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:2023.12.18

Position: GM Place:Zhejiang /China