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

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 60601-1-2:2015+A1:2020
EN 60601-1:2006+A1:2013
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: Ningbo Baichen Medical Devices Co., Ltd.
Address: Room 903, Diqu Building, 666 Taikang Middle Road, Ningbo, Zhejiang, CN

SRN:CN-MF-000021409

Product Information

Name: Electric Wheelchair
Model : BC-EA8000; BC-EA7001; BC-EA9000; BC-EA5516; BC-EA8001; BC-EA8002; BC-EA8003; BC-EA8004; BC-EA8005; BC-EA8006; BC-EA8007; BC-EA8008; BC-EA8009; BC-EA8010; BC-EA530X; BC-EA5513; BC-EALD3; BC-ES6001; BC-ES6003; BC-MS305; BC-MS306; BC-MS307; BC-MS308; BC-MS309; BC-MS310; BC-MS311; BC-MS312; BC-MS313
EMDN: Y122127
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: 2023.1.18

Position: GM Place: Ningbo/China