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: 2013
EN 60601-1-2:2015+A1:2020
EN 60601-1:2006+A1:2013
EN 12184: 2022

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 2101, 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-EALD4;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: 697518562ewheelchair001YK
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: 2025.1.1

Position: GM Place: Ningbo/China