DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR-000000247

Manufacturer

Name: Ningbo Baichen Medical Devices Co., Ltd.

Address: Room 2101, Diqu Building, 666 Taikang Middle Road, Ningbo, Zhejiang, CN

SRN: CN-MF-000021409

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019/A11:2021
ISO 15223-1:2021/Amd 1:2025
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 12184:2022
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021
EN 62366-1:2015

Product Information

Name: Electric Wheelchair

Model: Refer to Annex

EMDN: Y122127

Basic UDI-DI: 697518562ewheelchair001YK

Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-001.

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.

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: Alan Mao Date: 2025.6.9

Position: GM Place: Ningbo/China

File No.: MDR-TCF-001-09

Version: A/1

Annex

Electric Wheelchair	BC-ES6001, BC-ES6002, BC-ES6003, BC-ES6005, BC-ES6006, BC-ES6007, BC-ES6008, BC-ES6011, BC-ES8000, BC-ES5516, BC-EA8001, BC-EA8003, BC-EA8005, BC-EA8007, BC-EA8009, BC-EALD3, BC-EALD4, BC-EA8000, BC-EA8000F, BC-EA8000R, BC-EA8000MR, BC-EA8000FMR, BC-EA7000, BC-EA530X, BC-EA9000, BC-EA5516, BC-EA5517, BC-EA5518, BC-EA5519, BC-EM600, BC-EM606, BC-EM608, BC-EM609, BC-EM800, BC-EM806, BC-EM808, BC-EM809, BC-EM900, BC-EM906, BC-EM908, BC-EC8003, BC-EC8005, BC-EC8007, BC-EC8009, BC-EC8011, BC-EC8015, BC-EC8002, BC-EC8002HD, BC-EC8002-S, BC-EC8006, BC-EC8008, BC-EC8010, BC-EC8016, BC-EF1000, BC-EF1006, BC-EF1008, BC-EW01, BC-EW02, BC-EL01