

# 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

### 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.*


File No.: MDR-TCF-001-09  
Version: A/1

## 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

## 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: 2025.6.9

Position: GM Place: Ningbo/China

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

