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: 2022
EN 60601-1: 2006/A2: 2021
EN 60601-1-2: 2015/A1: 2021
EN 62366-1: 2015/A1: 2020

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 Youhuan Automation Technology Co., Ltd.

Address: No. 135, Xujia, Gujia Village, Jiangshan Town, Yinzhou District, Ningbo, Zhejiang, CN

SRN: CN-MF-000017295

Product Information

Name: Electric wheelchair

Model: YH-E7001, YH-E7001A, YH-E7001B, Yh-E7001F, YH-E7001R, YH-E7002, YH-E7003, YH-E7004, YH-E7005, YH-E7005A, YH-E7006, YH-E7007, YH-E7008, YH-E7009, YH-E7010, YH-E7011, YH-E7012, YH-E7013, YH-E6001, YH-E6001A, YH-E6002, YH-E6002A, YH-E6002B, YH-E6003, YH-E6004, YH-E6005, YH-E6005A, YH-E6005M, YH-E6006, YH-E6007, YH-E6010, YH-E6011, YH-E6011A, YH-E6012, YH-E6012A, YH-E6010, YH-E6012B, YH-E601102, YH-E601302, YH-E6013A, YH-E6013B, YH-E6016, YH-E7001MR, YH-E7014, YH-E7014R, YH-E7014MR, YH-E7007A, YH-E7007B, YH-E7007F, YH-E7007R, YH-E7007MR, YH-E8010, YH-E8011, YH-E8012, YH-E8013, YH-E8014, YH-E8015, YH-E8016, YH-E8017, YH-E8018, YH-E8019, YH-E8020, YH-E9010, YH-E9011, YH-E9012, YH-E9013, YH-E9014, YH-9015, YH-E9016, YH-E9017, YH-E9018, YH-E9019

EMDN: Y122127

Basic UDI-DI: 697502863YH01MT

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: [redacted] Date: 2025-02-27

Position: GM Place: Ningbo /China

宁波优环自动化科技有限公司
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