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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122124-02.

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: HEARTWAY MEDICAL PRODUCTS CO., LTD.
Address: No. 6, Gongyequ 25th Rd., Baoshan Vil., Nantun Dist., Taichung City 408017, Taiwan (R.O.C.)
SRN: TW-MF-000003315

Product Information

Name: Electric Scooter
Model:
PF2.PF7.PT7.PF7S.S8.S12.S16.S17.S19.S19F.S19V.S20.S21.S21F.S23.S26.PF6K.PF6K+.S11.S11+.S37.S37+.S40.S9.S38
EMDN: Y122124
Basic UDI: 471987123PSYV
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: 吳能逸 Date: May.25,2025.

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Position: Sales Place: Taiwan

台灣維順工業股份有限公司

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