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/A1:2021
EN 60601-1:2006/A2:2021
EN 12184: 2014
EN 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-02.

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: Kunshan Hi-Fortune Health Products Co., Ltd
Address: #625 Juxiang Rd, Zhangpu Town, Kunshan City, Jiangsu, CHINA
SRN: CN-MF-000035403

Product Information

Name: Electrically powered wheelchair
Model: HP358E、HP358EA、HP202、HP201、HP200、HP458E、EY07、EY18、P15、P55、HP203、HP204、HP205、HP206、HP207、HP208、HP209、HP210、HP211、HP212
EMDN: Y122127
Basic UDI-DI: 697385259Ewheelchair95
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: 20/5 2024

Position: GM

Place: Kunshan/China