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-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: Kunshan Aoshida Electric Technology Co.,Ltd
Address: No.6 Huanlou Road, Development Zone, Kunshan City, Jiangsu, China
SRN: CN-MF-000004204

Product Information

Name: Power wheelchair
Model: A05(T3), A06, A06L, A07, A08, A08C(DE08), A08L, A08CL(DE08L), A09, A10, A11, A12, A13,A15, A16,A17,A18,A19,A20,D05,D06,D07,D08,DE09, DE10,DE11,DE12,DE13,DE14,DE15
EMDN: Y122127
Basic UDI-DI: 697108640DYW50JF
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:2024.5.7

Position: GM Place:Jiangsu/China

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+A2:2020
EN 60601-1-2:2015+A1:2020

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: Kunshan Aoshida Electric Technology Co.,Ltd
Address: No.6 Huanlou Road, Development Zone, Kunshan City, Jiangsu, China
SRN: CN-MF-000004204

Product Information

Name: SCOOTER
Model: S1,S2,S3,S4,S5,S6,S7
EMDN: Y122124
Basic UDI-DI: 697108640SCOOTER35
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: 2024.5.7

Position: GM Place: Jiangsu/ China