



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-00000247

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,A12S
A13,A15,A16,A17,A18,A19,A20,A21,A22,A23,A24,A25
D05,D06,D07,D08,DE09,DE10,DE11,DE12,DE13,DE14,
DE15,DE16,DE17,DE18,DE19,DE20,GT13
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:

Position: GM

Date:2025.4.3

Place:Jiangsu/China

