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 12184:2014
EN 60601-1:2006+A1:2013+
AC:2014+A12:2014 +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-Y122124-01.

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: Shenzhen Zuowei Technology Co., Ltd.
Address: Floor 2nd, Building 7th, Yi Fenghua Innovation Industrial Park, Xinshi Subdistrict, Dalang Street, Longhua District, Shenzhen
SRN: CN-MF-000022824

Product Information

Name: Mobility Scooter
Model:ZW501,ZW502,ZW503,ZW504,ZW505,ZW506
EMDN: Y122124
GMDN: 45684
Basic UDI: 697415392ZW501PC
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: 2024.2.16

Position: GM Place: Shenzhen/China