



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/A11:2021
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5:2009/A11:2025
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/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 Zhimahuaerkai Technology Co.,
Ltd.
Address: 602 F1 BUILDING, TCL KEXUEYUANQU,
1001 ZHONGSHANYUAN RD., SHUGUANG
COMMUNITY, XILI STR., NANSHAN, SHENZHEN,
GUANGDONG CHINA
SRN: CN-MF-000039566

Product Information

Name: Mobility Scooter
Model: S3,S3 PRO, S1, S1 PRO, L5, L5 PRO
EMDN: Y122124
Basic UDI: 697641078PPX001RP
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: 2025.12.15

Position: GM Place: Shenzhen/China