



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-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: YONGKANG DAHAI INDUSTRY AND
TRADE CO.,LTD
Address: 3rd Floor ,Building 1,No. 68, Huacheng
West Road, Xicheng Street, YONGKANG,
ZHEJIANG, CHINA

SRN: CN-MF-000041909

Product Information

Name: MOBILITY SCOOTER
Model:
DH0305,DH0308,DH0319,DH0320,DH0321,DH0322
GMDN: 45684
EMDN: Y122124
Basic UDI-DI: 697757494MSEU014K
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: 2024.4.26

Position: GM

Place: Yongkang /China

