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 ISO 11199-2: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y120612-01.

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: Bradacare (XiaMen) Health Technology Co., LTD
Address: No.1368,Jicheng Road, Tong'an Area, Xiamen City(361100)China
SRN: CN-MF-000042118

Product Information

Name: Rollator
Model:
BR0001/BR0001-1/BR0001-2/BR0001-3,
BR0002/BR0002-1/BR0002-2/BR0002-3,
BR0003/BR0003-1/BR0003-2/BR0003-3/BR0003-5
BR0005/BR0005-1/BR0005-2/BR0005-3/BR0005-5
BR0006/BR0006-1/BR0006-2/BR0006-3/BR0006-5
EMDN: Y120612
Basic UDI-DI: 697717661BR001HC
Classification: Class I, According to Rule 1, 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: 2024.5.15

BRADACARE (XIAMEN) HEALTH TECHNOLOGY CO.,LTD 博尔瑞(厦门)健康科技有限公司 5020310328321

Position: GM Place: Xiamen /China