



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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

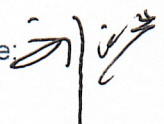
Name: Bradacare (XiaMen) Health Technology Co., LTD
Address: No.1368,Jicheng Road, Tong'an Area, Xiamen City(361100)China
SRN: CN-MF-000042118

Product Information

Name: Rollator
Model: See Annex
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

Position: GM

Place: Xiamen, China



Annex

Model:

BR0001/BR0001-1/BR0001-2/BR0001-3,
BR0002/BR0002-1/BR0002-2/BR0002-3,
BR0003/BR0003-1/BR0003-2/BR0003-3,
BR0005/BR0005-1/BR0005-2/BR0005-3,
BR0005PLUS, BR0005PLUS-1, BR0005PLUS-2, BR0005PLUS-3, BR0005PLUS-5,
BR0006/BR0006-1/BR0006-2/BR0006-3/BR0006-5/BR0006-6,
BR0006S, BR0006S-1, BR0006S-2, BR0006S-3, BR0006S-5, BR0006S-5,
BR0006F/BR0006F-1/BR0006F-2/BR0006F-3/BR0006F-5/BR0006F-6,
BR0006FS/BR0006FS-1/BR0006FS-2/BR0006FS-3/BR0006FS-5/BR0006FS-6,
BR808, BR808-1, BR808-2, BR808-3, BR808-5, BR808-6,
BR808S, BR808S-1, BR808S-2, BR808S-3, BR808S-5,
BR818, BR818-1, BR818-2, BR818-3, BR818-5,
BR818S, BR818S-1, BR818S-2, BR818S-3, BR818S-5, BR818S-6,
BR828, BR828-1, BR828-2, BR828-3, BR828-5, BR828-6