



DECLARATION OF CONFORMITY
ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: Shanghai Brother Medical Products
Manufacturer Co., Ltd
Address: 718, Fanou Modern Building, No 2449
Gonghexin Road, Jingan District, Shanghai City, China
SRN: CN-MF-000017485

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2016
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN 12183-2014

Remark


The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122103-01.
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.

Product Information

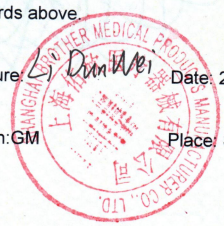
Name: Wheelchair
Model: Refer to Annex
EMDN: Y122103
Basic UDI-DI: 697512645BME460000TS
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

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: 2021.12.28

Position: GM Place: Shanghai /China



Annex

BME4611,BME4611C,BME4611D,BME4611M,BME4611S,BME4612,BME4613,BME4614,BME4615,
BME4616,BME4617,BME4618,BME4619,BME4620,BME4621,BME4622,BME4623,BME4624,BME4625,
BME4626,BME4627,BME4628,BME4629,BME4630,BME4631,BME4632,BME4633,BME4634,BME4635,
BME4636,BME4637,BME4638,BME4639,BME4640,BME4641,BME4642,BME4643,BME4644,BME4645,
BME4646,BME4647,BME4648,BME4649,BME4650,BME610,BME611,BME612,BME613,BME614,BME615,
BME661,BME662,BME663,BME664,BME665,BME666,BME667,BME668,BME669,BME670,BME6000,
BME6003,BME6004,BME6005,BME6008,BME6009,BME6015

