



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

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
IEC 60601-1:2005+A1:2012
IEC 60601-1-11:2015
IEC 60601-1-2:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080502-03.

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: XIAMEN SENYANG CO.,LTD
Address: No.189-1, Tongji South Road, Jimei
District, Xiamen, 361000, Fujian, P.R.China

Product Information

Name: POWERED NURSING TRANSFER LIFTS
Model: BMW01,BMW02,BMW03,BMW04
EMDN: V080502
Basic UDI-DI: 695207570006GH
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: Ping Wang

Position: GM

Date: 2021-11-25

Place: Xiamen/China

