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: 2013
EN 60601-1-2:2015+A1:2020
EN 60601-1:2006+A1:2013
EN 12184: 2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.

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: Zhejiang Innuovo Rehabilitation Devices Co.,Ltd
Address: No.196 Industy Road, Hengdian Movie Zone, Dongyang, Zhejiang, China
SRN: CN-MF-000008727

Product Information

Name: Power Wheelchair
Model:
N5513A,N5513B,N5513C,N5519,N5519D,W5211,W5213, W5213B,W5213C,W5213D,W5216,W5216A,W5216B,W5217, W5517,W5517A,W5520,W5521,W5521B,W5521C, W5211B,N5515,N5515A,N5516,N5516A,W5521A,N5525, W5526,N5901,W5907, W5536, W5536A, W5536B, N5913, Q50 R Carbon, N5915, N5916, N5517A, N5917, N5909, W5905, W5905A
EMDN: Y122127
GMDN: 40840
Basic UDI-DI: 697076597PW001QM
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.

浙江英洛华康复器材有限公司
ZHEJIANG INNUOVO REHABILITATION DEVICES CO., LTD

Signature: Grace Date: Feb. 28. 2023

Position: GM Place: Zhejiang/China