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 1041:2008+A1:2013
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN 12184:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMD-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: W5521(W5521-SIL) (#IFPC17SIL), W5517(W5517-BLK) (#AFPC17BLK)

GMDN: 40840

Basic UDI-DI: 697076597PW001QM

Intended purpose: The product is intended to provide transportation for disabled or elderly persons limited to a seated position.

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: Sept. 22, 2021

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

Position: GM Place:Zhejiang/China