



# 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-00000247

### 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.

Signature: *Grace* Date: *Feb. 28. 2023*

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

Position: GM

Place: Zhejiang/China