

MD

# DECLARATION OF CONFORMITY

ACCORDING TO MEDICAL DEVICES ORDINANCE OF 1 JULY 2020

## CH Representative

**SUNGO Technical Service GmbH**  
**Bahnhofstrasse 21,6300 Zug, Switzerland**

## Conformity Assessment

### Conformity Assessment Procedure

Section 1, Chapter 3 of Medical Devices  
Ordinance of 1 July 2020

### 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/A1:2021  
EN 60601-1:2006/A2:2021  
EN 12184: 2014

### Remark

*The declaration of conformity is valid in connection  
with the release technical document CH/MEDDO-  
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 Industry Road, Hengdian Movie Zone,  
Dongyang, Zhejiang, China

## Product Information

**Name:** Power Wheelchair

**Model:** Q50 R Carbon

**EMDN:** Y122127

**Classification:** Class I, According to Section2,  
Chapter2 of Medical Devices Ordinance of 1 July 2020

## Declaration

We herewith declare that the above-mentioned  
products meet the requirements of Medical Devices  
Ordinance of 1 July 2020 and the applicable standards  
above.

Signature:

Date:

Apr. 07. 2023

Position: GM

Place: Zhejiang /China

