



# 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: 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 12182: 2012

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-V080502-02.*

*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: Shenzhen Zuowei Technology Co.,Ltd.  
Address: Floor 2nd, Building 7th, Yi Fenghua innovation industrial park, Xinshi Subdistrict, Dalang street, Longhua District, Shenzhen

## Product Information

Name: Electric lift transfer chair

Model: ZW387D ZW388D ZW389D

EMDN: V080502

Basic UDI-DI: /

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:  Date: 2022.2.16

Position: GM Place: Shenzhen/China

