



# 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: 2016  
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

## Manufacturer

**Name:** Ningbo Youhuan Automation Technology Co., Ltd  
**Address:** No. 135, Xujia, Gujia Village, Jiangshan Town, Yinzhou District, Ningbo, Zhejiang, CN  
**SRN:** CN-MF-000017295

## Product Information

**Name:** Electric wheelchair

**Model :** YH-6001, YH-6002, YH-6003, YH-6004  
YH-6005, YH-6006, YH-6010, YH-6011, YH-6011-A  
YH-7001, YH-7001A, YH-7002, YH-7003, YH-7004  
YH-7005  
YH-E7001A , YH-E7001B , Yh-E7001F,  
YH-E7001R , YH-E7003 , YH-E7006 , YH-E7007 ,  
YH-E7008 , YH-E7009 , YH-E7010 , YH-E7012,  
YH-E7005, YH-E7005A, YH-E6012, YH-E6001,  
YH-E6001A, YH-E6002A, YH-E6002, YH-E6003,  
YH-E6012A, YH-E6006, YH-E6005M, YH-E6003,  
YH-E6005, YH-E6005A, YH-E6002B, YH-E6006,  
YH-E6007, YH-E6011, YH-E6011A, YH-E6005M,  
YH-E7011, YH-E7013

**EMDN:** Y122127

**Basic UDI-DI:** 697502863wheelchairS3

**Classification:** Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

## Declaration

**Remark**


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*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.*

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:

2024.3.28

Position: GM

Place: Ningbo/China

