



# 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-000000247

## Conformity Assessment

**Conformity Assessment Procedure**  
Annex II, III +IV of Regulation (EU)  
2017/745

**Applicable Standards**  
EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN 1041:2008+A1:2013  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-JBH03. 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:** Anhui JBH Medical Apparatus Co., Ltd  
**Address:** No. 116 qicang Road, Mingguang City, Chuzhou, Anhui, China  
**CN-MF-000008809**

## Product Information

**Name:** Electric Wheelchair  
**Model:** D09  
**GMDN:** 40855  
**Intended Purpose:** A wheeled personal mobility device, It consists of a seat support system and motor propulsion system for the disabled, the control of speed and direction is performed by the user.

### Basic UDI-DI:

Electric Wheelchair	D09	697317553JBHD0902TZ
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**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

Position: GM

Place: Anhui/China

