



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 of Regulation (EU) 2017/745

Applicable Standards

- EN ISO 14971:2019+A11:2021
- EN ISO 15223-1:2021+A1:2025
- EN ISO 20417:2021
- EN ISO 10993-1:2025
- EN ISO 10993-5:2009+A11:2025
- EN ISO 10993-10: 2023
- EN ISO 10993-23:2021+A1:2025
- EN 12184:2022
- EN 60601-1:2006+A13:2024
- EN 60601-1-2:2015+A1:2021

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

Anhui JBH Medical Apparatus Co., Ltd
No. 116 qicang Road, Mingguang City, Chuzhou,
Anhui, China
SRN: CN-MF-000008809

Product Information

Name: Electric Wheelchair
Model: D26,D39,DC10M,DC10L
EMDN: Y122127

Basic UDI-DI:

Model	MD Class	Basic UDI-DI
D26	1	697317553JBHD2602TY
D39	1	697317553JBHD3902UN
DC10M	1	697317553JBHDC10M02S6
DC10L	1	697317553JBHDC10L02RZ

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

Intended purpose: Aids for the movement of people with reduced mobility

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: 2026.03.26

Position: GM 3411820154 Place: Anhui/China