



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Manufacturer

EU Representative

Name: SUNGO Europe B.V.
Address: Fascinatio Boulevard
522, Unit 1.7, 2909VA Capelle
aan den IJssel, The Netherlands
SRN: NL-AR-000000247

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

Product Information

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: 2023; EN ISO
10993-23: 2021; EN 12184:2014;
EN 60601-1:2006/A2:2021; EN
60601-1-2:2015/A1:2021; EN
62366-1:2015

Name: Electric Wheelchair

Model: D01, D02, D03, D05, D06, D07, D08, D09, D10, D11, D12,
D13, D14, D15, D16, D17, D18, D19, D20, D21, D22, D23, D26, Z01,
Z02, Z03, Z04, DC01, DC02, DC03, DC04, DC05, D09B, D09C,
D09D, D09E, D10A, D10B, D10C, D10D, D10DB, D12C, D15A,
D15C, D15B, D19B, D25, D29, D29A, D30, D36, D37, D39, DC06, D50
DC07, DC07A, DC07L, DC07S, DC07E, DC07M, DC08, DC08A, DC08L,
DC08S, DC08E, DC08M, DC09, DC09L, DC09S, DC09E, DC10, DC10A,
DC10L, DC10S, DC10E, DC10M ;

EMDN: Y122127

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:

2024.5.7

Position: GM

Place: Chuzhou/China

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.*