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: 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

Product Information

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

GMDN: 40855

Basic UDI-DI: /

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: 2021.4.1

Position: GM Place: Anhui/China