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 +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

Product Information

Name: Electric Scooter
Model: FDB01、FDB02、FDB05、FBC01
GMDN: 45684
Basic UDI-DI: See annex

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: 魏之伟 Date: 2021.7.1

Position: GM Place: Anhui/China

Annex

Name	Model	Basic UDI-DI
Electric Scooter	FDB01	697317553JBHFDB0102UW
Electric Scooter	FDB02	697317553JBHFDB0202V3
Electric Scooter	FDB05	697317553JBHFDB0502VJ
Electric Scooter	FBC01	697317553JBHFBC0102UF

Signature: 魏涛

Date: 2021.7.1

Position: GM

Place: Anhui/China