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
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 60601-1-2:2015/A1:2021
EN 60601-1:2006/A2:2021
EN 12184: 2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YF-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

Name: IF Health （Xiamen) Intelligent Technology Co.,Ltd

Address: Zone A, 4th floor, No.3 building, No.66, xiangyue Rd, Torch high-tech zone (xiang'an) industrial zone, Xiamen, Fujian, China.

SRN: CN-MF-000013208

Product Information

Name : Electric Wheelchair

Model : YFLB-01、YFNB-01、YFWB-01、YFLB-03、YFNB-03 、 YFWB-03 、 YFNB-12 、 YFNB-13 、YFNB-22 、 YFNB-23 、 YFWB-22 、 YFWB-23 、YFWB-32 、 YFWB-33 、 YFWB-42 、 YFWB-43 、YFWB-62、YFWB-63、YFWB-52、 YFWB-53

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: 2023/4/19

Position: GM Place: Xiamen/China