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

Manufacturer

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

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

SRN: TBD

Product Information

Name: Electric Wheelchair

Model: YFLB-01, YFNB-01, YFWB-01

GMDN: 40840

Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

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
ISO 7176: 2019
EN 60601:2015
IEC 60601:2014
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.

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:

Position: Chairman

Date: 2021.7.23

Place: Fujian/China