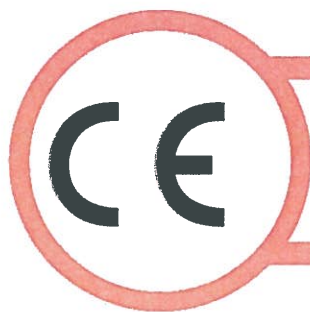




DECLARATION OF CONFORMITY

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

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.

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

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

