

SUZHOU KD INTELLIGENT DEVICE CO., LTD.

NO.36 Gugang Road, Chengxiang Town, Taicang City, Jiangsu P.R. of China

TEL: +86-512-53110088 FAX: +86-512-53110099

Declaration of Conformity

Manufacturer

Suzhou KD Intelligent Device Co., Ltd. located in No.36 Gugang Road, Taicang City, Jlangsu Province, China.

European

Distributeur France Acekare

Representative

7 rue de Mireport 33310 LORMONT - 09 80 80 8515

Product Name:

Power wheel chair

Models:

PL001-1002, PL001-4001, PL001-4002, PL001-2004-1, PL001-2009, PL001-2010, PL001-2003K, PL001-3005, PL001-2004, PL001-6001, PL001-6002, PL001-7001, PL001-7002, PL001-7003, PL001-5001

UMDNS Code:16214

Medical Device Classification: Class I

Basic UDI -DI: 697057522

Conformity Assessment Route: ANNEX II & ANNEX III of Regulation (EU) 2017/745: CLASSIFICATION RULES, NON-INVASIVE DEVICES:

Rule1(ANNEX VIII)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council regulations and Standards. All supporting documentations are retained under the premises of the manufacturer.

REGULATIONS

General applicable regulations:

Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on Medical devices (MDR)

EN 12184:2009; ISO7176; ISO9999:2011, EN60601-1-2: 2016

Taicang, Suzhou, China

Mar, 01, 2021

Signature:

yinon zhang

Name:

Yiwen Zhang

Position:

General Manager

EC Declaration of Conformity

SZKD CE-01(A/0)

