

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Dragon Medical Co.,Ltd
Room B2313-B2314, 13 block of Injoy Plaza, Yangshe Town,
Zhangjiagang City, Jiangsu Province, China

Trademark:**SRN:**

CN-MF-000011438

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN:

DE-AR-000000087

Product name:

Stair climbing wheelchair

Product model:

DW-ST003A、DW-ST003B、DW-ST003C、DW-SW01、
DW-SW02、DW-SW03A、DW-SW03B、DW-SW04、
DW-SW05、DW-11A、DW-11B、DW-11C、DW-11D、
DW-LH-01、DW-LH-02、DW-SW03、DW-SW02A、DW-SW06、
DW-SW07、DW-SW08A、DW-SW08B、DW-MINIA、DW-MINNB、
DW-MINIC、DW-MINID、DW-FL01、DW-FL02、DW-FL03、DW-FL04、
DW-FL05、DW-EST00C、DW-EST01C、DW-EST01S、DW-EST90C、
DW-EST001、DW-EST120、DW-SW09、DW-SW09B、DW-SW10、
DW-SW11、DW-SW11B、DW-SW12、DW-SW13、DW-SW14、
DW-SW15、DW-SW15B、DW-11C-A、DW-11C-B、DW-11E、DW-11F

Intended Use

It is used for transporting and moving patients in medical institutions.

Basic UDI:

697467901DWSCTL

EMDN code

Y122199

Classification acc. to MDR Ax. VIII:

Class 1, rule 1

Applied Standard & Common

EN ISO 13485:2016/AC:2018, EN ISO 14971: 2019

Specification:

En ISO10993Series, EN ISO 15223-1:2021

Conformity assessment procedure: Annex II+ Annex III of Regulation EU 2017/745(MDR)

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Kelly He, General Manager


Zhangjiagang, 05,05,2024

江苏隆世洲医疗科技有限公司
Dragon Medical Co., Ltd.