

EU DECLARATION OF CONFORMITY



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

Manufacturer: Dragon Medical Co.,Ltd.
No.252, West Second Ring Road, Yangshe Town, Zhangjiagang City
, Suzhou City, Jiangsu Province,China,215600

Trademark: 

SRN: CN-MF-000011438

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

SRN: DE-AR-000000087

Product name: Manual wheelchair

Product model: C295-WC01,C295-WC02,C295-WC04,C295-WC05,C295-WC06,C295-WC07,C295-WC08,
DW-WC09,M218-525,M218-471,M248-807LJ-07,M239-12F,M248-807LJ-10,M248-807LJ-11,
M239-8F-45,M239-8F,M239-F7-22,KJT112,KJT605,DW-803,DW-WC605,DW-WC08,DW-980C,
WFCO01,DW-S601,DW-081F3,DW-MW2404,DW-MW2405,DW-MW2406,DW-MW2407,
DW-MW2408,DW-MW01,DW-MW2409,DW-MW2410,DW-MW2411,DW-MW2412,DW-MW2413,
DW-MW2414,DW-MW2415,DW-MW2416,DW-MW2417,DW-MW2418,DW-MW2419,DW-MW2420,
DW-MW2421,DW-MW2422,DW-MW2423,DW-MW2424,DW-MW2425,DW-MW2426

Intended Use It is used to compensate the transport and walking function of patients
with mobility disorders.

Basic UDI-DI: 697467901DWMWUA

EMDN code Y1221

Classification acc. to MDR Class 1, rule 1

Ax. VIII:

Applied Standard & Common Specification: EN ISO 13485:2016/AC:2018, EN ISO 14971: 2019
En ISO10993 Series, EN ISO 15223-1:2021

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

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

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, 2026.05.14

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