



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-00000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 12184:2022
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-LSZ06.
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.

Manufacturer

Name: Dragon Medical Co.,Ltd
Address: Room B2313-B2314, 13 block of Injoy Plaza, Yangshe Town, Zhangjiagang City, Jiangsu Province, China
SRN:CN-MF-000011438

Product Information

Name: Electric Wheelchair
Model: DW-WD301, DW-WD1801, DW-WD501, DW-WD501E, DW-ND701, DW-601, DW-WD602, DW-WD1003, DW-WB802, DW-WD901, DW-C001, DW-001, DW-308, DW-510EX(001), DW-602P, DW-605J, DW-605JX, DW-6011, DW-702LJ, DW-703, DW-703LJ, DW-704, DW-710, DW-753, DW-W8013, DW-W8015, DW-980C, DW-CO01N, DW-CO02N, DW-Y01B, DW-Y01C, DW-DY112, DW-DY113, DW-JW62, DW-JW69, DW-W2, DW-W3, DW-W5, DW-W6, DW-W6016, DW-WC03, Dragon Gilde Flex, WD901, C164-1108L, M155-SC, M155-SS, M193-601P, M196-EWCA, M293-Y15, M239-Y16, M239-Y7, M248-701(2), M248-701(3), M248-701(4), M248-701(5), M248-702LJ, M248-807, 293-Y15, 293-Y16, 293-Y7

EMDN: Y122127

Basic UDI-DI: 697467901DWEWTJ

Classification: Class I, According to Rule 13, 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: GM

江苏隆世洲医疗科技有限公司
Date: 2024.11.21
Dragon Medical Co.,Ltd

Place: Zhangjiagang/China