



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

MedUnion S.L.
Carrer de Tapioles, 33, 2-1,
08004 Barcelona, Spain
SRN: ES-AR-000019366

Manufacturer

Jiangxi Jiangte Electric Vehicle Co., Ltd.
No.12 Chunchao Road, Economic Development
Zone, Yichun City, Jiangxi Province, China
SRN: CN-MF-000026965

Conformity Assessment

Conformity Assessment Procedure
Annex IX of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-5: 2009
EN ISO 10993-10:2021
EN ISO 10993-23:2021
EN 12184:2014+ISO 7176
IEC 60601-1-2:2014+A1:2020
EN 60601-1-2:2015+A1:2021
EN ISO 7176-21:2009

Remark

The Declaration of Conformity is valid in connection with the release technical document CE/MDR-Y120606-01.

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: Mobility Scooter
Model: FM10 Series: R100, R103, FM10
R300S series: R300S, R300, R301,
R301S, FM30, JT30, DC30, R500
JT10 series: JT10, JT20, DC10, DC20

GMDN:
EMDN: Y120606
Basic UDI-DI: 697312408MB01EB
Classification: Class I, According to Rule 13,
Annex VIII, Regulation (EU) 2017/745 MDR

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: 

Name: Yang, Jing

Position: GM

