



佛山市南海锐麟铝制品有限公司
Ralon Medical Equipment Co.,Ltd

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EU DECLARATION OF CONFORMITY

Manufacturer: Ralon Medical Equipment Co., Ltd

Xilian Development Zone, Jinsha Danzao, Nanhai Foshan, Guangdong,
China

European Representative: Obelis s.a.

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Representative: Mr. Gideon ELKAYAM (CEO)

Product Name: Rollator

Model Number:

RL-A42046C (700300100 Nitro SL grey),
RL-A42046C (700300200 Nitro SL white),
RL-A42046C (700300300 Nitro SL light blue),

UDI-DI:

RL-A42046C (700300100 Nitro SL grey) : 06973142310570
RL-A42046C (700300200 Nitro SL white) : 06973142310662
RL-A42046C (700300300 Nitro SL light blue) : 06973142310846

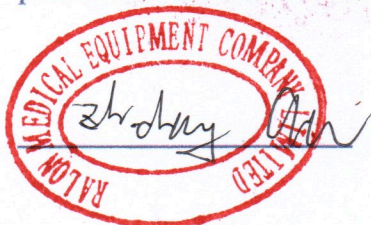
Classification (MDR 2017/745 Annex VIII) : Class I, Rule 1

Conformity Assessment Route: MDR 2017/745 Article 19, Annex II, Annex III

Applicable Standards:

DIN EN ISO 11199-2:2021 Walking aids manipulated by both arms - Requirements and
test methods - Part 2: Rollators
DIN EN ISO 13485:2016 Quality management systems - Requirements for regulatory
purposes
EN ISO 14971-2012 Application of Risk Management to Medical devices.

We herewith declare that this EU declaration conformity is issued under the sole responsibility of the manufacture. The products mentioned above is in conformity with the EU Medical Device Regulation 2017/745. All supporting documentations are retained under the premises of the manufacture.



Issue place and date : Foshan, 2022.12.20