



ISO13485:2016

锐麟铝制品有限公司

Ralon Medical Equipment Co., Ltd

厂址: 广东省佛山市南海区丹灶镇金沙西联开发区

电话 (TEL): 0757-86607838 86615283 传真 (FAX): 0757-86610593

Email: [jane.li@ralon-medical.com](mailto:jane.li@ralon-medical.com) Website: <http://www.ralon-medical.com>

## EC DECLARATION OF CONFORMITY

We, Ralon Medical Equipment Co., Ltd, Xilian Development Zone, Jinsha Danzao, Nanhai Foshan, Guangdong, China, hereby declare under our own responsibility that the following product:

Product Name: ULTRALIGHT Rollator

Product Code: SA1314001

Meet the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them.

The abovementioned devices have been classified as class I devices according to rule I

This declaration is supported by the Quality Management System certification:

No. Q2N 15 08 71157 003, EN ISO 13485:2012 + AC:2012 Medical devices- Quality management systems issued by TÜV SÜD PRODUCT Service GmbH-Zertifizierstelle-Ridierstraße 65, 80339 München, Germany

This declaration is based on the conformity assessment of products to the requirements of Annex VII

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer"

Foshan, China

Issue place and date (14/12/2018)

<Stamp>

European Authorized Representative:

<Manufacturer's Signature>

<Name> Zhicheng Chen

<Position> General Manager

Registered Address:

Obelis s.a.

Bd. Général Wahis 53

B-1030 Brussels, Belgium

Phone: 32.2.732.59.54

Fax: 32.2.732.60.03

E-mail: [mail@obelis.net](mailto:mail@obelis.net)

Representative: Mr. Gideon ELKAYAM (CEO)