

## 佛山市南海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 传真(FAX): 0757-86610593

Email: ralon@ralon-medical.com

### **DECLARATION OF CONFORMITY**

We, Ralon Medical Equipment Co., Ltd and address Xilian Development Zone, Jinsha Danzao, Nanhai Foshan, Guangdong, China hereby declare under our sole responsibility that the product(s) listed in Annex comply(ies) with the provisions of the Medical Device Regulations 2002 (SI 2002 n. 618) (UK MDR 2002) as amended by Medical Device regulations (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020 n. 1478) (UK MDR 2020).

The Manufacturer has designated the following UK responsible person within the UK:

Obelis UK Ltd. Sandford Gate Oxford OX4 6LB United Kingdom

Phone: +44.1491.378012

E-mail: info@obelis.co.uk

The devices are Class 1 following Rule 1 of Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2020)

The medical devices meet the provisions of Annex I (as modified by Part II of Schedule 2A to the UK MDR 2020).

The following conformity procedure has been applied in order to affix the UKCA marking on the devices:

Class 1: the procedure referred to in Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2020)

This Declaration is valid for all products bearing the UKCA marking placed on the UK Market as of the date of signature of this Declaration.

Zhiohay Olm <Manufacturer's Signature>

Issue place and date (DD/MM/YY) 28/10/2022 <N

<Name> Zhicheng Chen

<Stamp> < Position> President

Attachments –DoC Medical devices— V1 - 28/04/2021 Page **1** of **3** 



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#### **Annex to Declaration of Conformity**

No.	Cat. Ref N.	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD code	UDI	Class	Rule
1.		RL-S42014	Steel Rollator	3 wheeled frame including a seat, backrest and shopping bag.;  A mobility aid used to assist the user in walking by providing a means of support and increasing their ability to move around without attendance from another person.	37951	6973142310693	1	1
3.		RL-A42053 RL-A42108	- Aluminum Rollator	4 wheeled frame including a seat, backrest and shopping bag.  A mobility aid used to assist the user in walking by providing a means of support and increasing their ability to move around without attendance from another person.	37951	6973142310921 06973142310921	1	1
4.		RL-A42105W8				6973142310891		
5.		RL-A42105W10				6973142310877		
6.		RL-A42089S				6973142310938		
7.		RL-A42089L				6973142310945		
8.		RL-A42056KD				6973142310952		
9.		RL-A42043				6973142310327		
10.		RL-A42016				6973142310259		
11.		RL-A42068				6973142310068		
12.		RL-A42012	Aluminum Rollator	4 wheeled frame including a seat, backrest and shopping bag.  A mobility aid used to assist the user in walking by providing a means of support and increasing their ability to move around	37951	6973142310013	1	1
13.		RL-A41020				6973142310167		
14.		RL-A42058				6973142310099		
15.		RL-A42018KD				6973142310044		



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16. 17. 18.	RL- A42094PNW10 RL-A42045W6 RL-A42045W8		without attendance from another person.		6973142310839 6973142310136 6973142310969		
19.	RL-A42046C				6973142310310		
20.	RL-A42020				6973142310914		
21.	RL-A42024	Aluminum Rollator	3 wheeled frame including a seat, backrest and shopping bag.  A mobility aid used to assist the user in walking by providing a means of support and increasing their ability to move around without attendance from another person.	37951	6973142310976	1	1
22.	RL-A42024KD				6973142310983		
23.	RL-A42104KD				6973142310990		
24.	RL-A42024S				6973142310822		
25.	RL-S41006	Steel Rollator	3 wheeled frame including a seat, backrest and shopping bag.  A mobility aid used to assist the user in walking by providing a means of support and increasing their ability to move around without attendance from another person.	37951	6973142310006	1	1
26.	RL-S42043				6973142310655		
27.	RL-S42034W				6973142310242		