



# Formulier

## EC declaration of conformity RO4150, wheeled walker 2<sup>nd</sup> generation Modification underarmsupport

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Document ECD. 1.1.2.2.2  
RO4150 wheeled walker

Procedure- Kwaliteitscoördinator

Revisiedatum 06-01-2020

### Revisies

Revisie	Datum (dd-mm-jjjj)	Auteur	Beschrijving van de wijziging
1.0	6-1-2020	R.Keuning	Geïmplementeerd bij Premis

**Manufacturer's name:** Premis Medical BV  
**Business:** De nort 20  
 3931 NG Woudenberg  
 The Netherlands  
**Product:** (RO4150)  
**Classification:** Class 1 = light risk class

### Confirm solely responsible that the following Medical devices:

	Article No.	Class
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 20cm underarmsupport left, standard height. Standard handgrip right.	RO4150AELOLXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 20cm underarmsupport left, reduced height. Standard handgrip right.	RO4150AELVLXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 28cm underarmsupport left, standard height. Standard handgrip right.	RO4150AELPLXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 28cm underarmsupport left, reduced height. Standard handgrip right.	RO4150AELWLXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 20cm underarmsupport right, standard height. Standard handgrip left	RO4150AELORXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 20cm underarmsupport right, reduced height. Standard handgrip left	RO4150AELVRXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 28cm underarmsupport right, standard height. Standard handgrip left	RO4150AELPRXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 28cm underarmsupport right, reduced height. Standard handgrip left	RO4150AELWRXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 20cm underarmsupport left and right, standard height.	RO4150AELORXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 20cm underarmsupport left and right, reduced height.	RO4150AELVXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 28cm underarmsupport left and right, standard height.	RO4150AELPXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) XL 50cm, user weight 150kg. Red with 28cm underarmsupport left and right, reduced height.	RO4150AELWXXX	1

### Fulfil the relevant requirements of medical devices according to the:

**EC regulation 93/42/EEC**

NEN: EN:IEC 62366-1:2015

NEN: EN:ISO 15223-1:2016

NEN: EN:ISO 14971-1:2015

NEN: EN:ISO 11199-2:2005

CEN: EN:1985:1998

The corresponding technical documentation is available to be examined.

**This document also applies to the colour blue (B). Position 7 in the article number refers to the colour of the wheeled walker.**

Versie:	1.0	Classificatie:	Voor Intern gebruik/Publiek
Status:	In gebruik		
Datum:	06-01-2020	Auteur:	R.Keuning

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RO4150, wheeled walker 2<sup>nd</sup> generation  
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Explanation

**NEN: EN:IEC 62366-1:2015**

Medical devices - Application of usability engineering to medical devices

**NEN: EN:ISO 15223-1:2016**

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

**NEN: EN:ISO 14971-1:2015**

Medical devices - Application of risk management to medical devices

**NEN: EN:ISO 11199-2:2005**

Walking aids manipulated by both arms - Requirements and test methods -

**CEN: EN:1985:1998**

Walking aids - General requirements and test methods

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2020

Special variations

- Pressure brake – the third letter after RO4150 changes from a L to a D.
- Unilateral braking system left – the sixth letter after RO4150 changes from a X to a L
- Unilateral braking system right – the sixth letter after RO4150 changes from a X to a R
- Passive braking system – the seventh letter after RO4150 changes from a X to an A

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