

**EC declaration of conformity
RO4143, wheeled walker 2nd generation
Modification underarmsupport**

Pagina 1 van 3

Document ECD. 1.1.2.1

Procedure-
verantwoordelijke Kwaliteitscoördinator

Revisiedatum 9-12-2019

Revisies

Revisie	Datum (dd-mm-jjjj)	Auteur	Beschrijving van de wijziging
1.0	3-1-2020	R.Keuning	Geïmplementeerd bij Premis

Manufacturer's name: Premis Medical BV

Business: De nort 20
3931 NG Woudenberg
The Netherlands

Product: (RO4143)

Classification: Class 1 = light risk class

SRN number: NL-MF-000005783

Udinummer: 08718874133459, 08718874134104, 08718874133848, 08718874134494,
08718874133589, 08718874134234, 08718874133978, 08718874134623,
08718874133329, 08718874134883, 08718874133718, 08718874134364,

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Status:	In gebruik		
Datum:	03-01-2020	Auteur:	R.Keuning

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Confirm solely responsible that the following Medical devices:		
	Article No.	Class
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 20cm underarmsupport left, standard height. Standard handgrip right.	RO4143AELOLXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 20cm underarmsupport left, reduced height. Standard handgrip right.	RO4143AELVLXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 28cm underarmsupport left, standard height. Standard handgrip right.	RO4143AELPLXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 28cm underarmsupport left, reduced height. Standard handgrip right.	RO4143AELWLXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 20cm underarmsupport right, standard height. Standard handgrip left	RO4143AELORXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 20cm underarmsupport right, reduced height. Standard handgrip left	RO4143AELVRXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 28cm underarmsupport right, standard height. Standard handgrip left	RO4143AELPRXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 28cm underarmsupport right, reduced height. Standard handgrip left	RO4143AELWRXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 20cm underarmsupport left and right, standard height.	RO4143AELOXXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 20cm underarmsupport left and right, reduced height.	RO4143AELVXXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 28cm underarmsupport left and right, standard height.	RO4143AELPXXX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg. Red with 28cm underarmsupport left and right, reduced height.	RO4143AELWXXX	1
Fulfil the relevant requirements of medical devices according to the: MDR:2017-745 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 colours blue (B), apple green (G), black (Z), titanium (T), white (W), purple (P) and orange (O). position 7 in the article number refers to the colour of the wheeled walker		

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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

MDR: 2017-745

Medical device Regulation- Application for Medical Devices

Special variations

- Pressure brake – the third letter after RO4143 changes from a L to a D.
- Unilateral braking system left – the sixth letter after RO4143 changes from a X to a L
- Unilateral braking system right – the sixth letter after RO4143 changes from a X to a R
- Passive braking system – the seventh letter after RO4143 changes from a X to an A

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2022

Valid Till end of 2022

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