

**EC declaration of conformity
RO4143, wheeled walker 2nd generation
Modification One sided brake**

Pagina	1 van 2
Document	ECD. 1.1.2.1.4-RO4143 Wheeled walker
Procedure- verantwoordelijke	Kwaliteitscoördinator
Revisiedatum	3-1-2020

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: 08718874134678, 08718874138072, 08718874777257, 08718874131271,
 08718874127878, 08718874124471, 08718874121074, 08718874117671

Confirm solely responsible that the following Medical devices:		
	Article No.	Class
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg Red with a standard brace one sided Right	RO4143AELXXRX	1
Wheeled walker Provo 2 nd generation (rollator) user weight 120kg Red with a standard brace one sided Left	RO4143AELXXLX	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		

Versie:	1.0	Classificatie:	Voor Intern gebruik/Publiek
Status:	In gebruik		
Datum:	03-01-2020	Auteur:	R.Keuning

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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.
- Unlateral braking system left – the sixth letter after RO4143 changes from a X to a L
- Unlateral 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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