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Procedure- verantwoordelijk	Kwaliteitscoördinator
Revisiedatum	3-1-2020

## EC declaration of conformity RO4143 – Wheeled walker

### 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:** 08718874111662, 08718874138157, 08718874777332, 08718874131356,  
 08718874127953, 08718874124556, 08718874121159, 08718874117756

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

	Article No.	Class
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Red	RO4143AELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Blue	RO4143BELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Apple green	RO4143GELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Purple	RO4143PELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Orange	RO4143OELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Black	RO4143ZELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg White	RO4143WELXXXX	1
Wheeled walker Provo 2 <sup>nd</sup> generation (rollator) user weight 120kg Titanium	RO4143TELXXXX	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

The corresponding technical documentation is available to be examined.

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.
- 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, 2023

Valid Till end of 2023

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