

Formulier

EC declaration of conformity RO4150 – Wheeled walker

Pagina 1 van 2

Document ECD.1.1.2.2.2 RO4150
Wheeled walker

Procedure-
verantwoordelijk 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: (RO4150)
Classification: Class 1 = light risk class
SRN number: NL-MF-000005783
Udinummer: 08718874550003, 08718874485404

Confirm solely responsible that the following Medical devices:

	Article No.	Class
Wheeled walker Provo 2 nd generation (rollator) XL 50cm user weight 150kg Red	RO4150AELXXXX	1
Wheeled walker Provo 2 nd generation (rollator) XL 50cm user weight 150kg Blue	RO4150BELXXXX	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 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

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2022

Valid Till end of 2022

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