

**EC declaration of conformity
EL7817 Elbow crutch**

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: EL7817

Classification: Class 1 = light risk class

SRN number: NL-MF-000005783

Udinummer: 08718874363108, 08718874363054, 08718874788468, 08718874363092,
08718874363078, 08718874363115, 08718874362897, 08718874363313,
08718874815997, 08718874363269, 08718874816000, 08718874788499,
08718874816017, 08718874363306, 08718874816024, 08718874363283,
08718874816031, 08718874816048, 08718874363320, 08718874815980,
08718874362958, 08718874815973, 08718874363382, 08718874363337,
08718874788505, 08718874363375, 08718874363351, 08718874363344,
08718874363399, 08718874362972, 08718874363030, 08718874362989,
08718874363023, 08718874363009, 08718874362996, 08718874363047,
08718874362866, 08718874363177, 08718874363122, 08718874363160,
08718874363146, 08718874363139, 08718874363184, 08718874362910,
08718874363245, 08718874363191, 08718874363238, 08718874363214,
08718874363207, 08718874363252, 08718874362934

Versie:	1.0	Classificatie:	Voor Intern gebruik/Publiek
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
Premis EL7817 pair elbow crutches, anatomical handgrip in angle adjustable closed cuff, colour black	EL7817PAPZW	1
Premis EL7817 left elbow crutch, anatomical handgrip in angle adjustable closed cuff, colour black	EL7817PALZW	1
Premis EL7817 right elbow crutches, anatomical handgrip in angle adjustable closed cuff, colour black	EL7817PARZW	1
Premis EL7817 pair elbow crutches, anatomical handgrip in angle adjustable open cuff, colour black	EL7817PCPZW	1
Premis EL7817 left elbow crutch, anatomical handgrip in angle adjustable open cuff, colour black	EL7817PCLZW	1
Premis EL7817 right elbow crutch, anatomical handgrip in angle adjustable open cuff, colour black	EL7817PCRZW	1
<p>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 12182:1999 CEN: EN:1985:1998</p> <p>The corresponding technical documentation is available to be examined.</p> <p>This document also applies to the colours blue (BL), bronze (BR), black (ZW), green (GR), White (WI), red (RO) and Silver (SI). position 10 and 11 in the article number refers to the colour of the crutches</p>		

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Document	ECD.1.2.1 EL7817 Elbow crutch
Procedure- verantwoordelijke	Kwaliteitscoördinator
Revisiedatum	03-01-2020

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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 12182:1999

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

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2022

Valid Till end of 2022

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