

**EC declaration of conformity  
EL7804 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:** EL7804

**Classification:** Class 1 = light risk class

**SRN number:** NL-MF-000005783

**Udinummer:** 08718874401350, 08718874401220, 08718874401343, 08718874401411,  
08718874401299, 08718874401404, 08718874401398, 08718874401275,  
08718874401381, 08718874401374, 08718874401251, 08718874401367,  
08718874401459, 08718874401336, 08718874401442, 08718874401435,  
08718874401312, 08718874401428

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

	Article No.	Class
Premis EL7804, pair elbow crutches normal, anatomic cumfy handgrip, closed cuff, aluminium, blue or black	EL7804PAPAL	1
Premis EL7804, pair elbow crutches normal, anatomic cumfy handgrip, open cuff, aluminium, blue or black	EL7804PCPAL	1
Premis EL7804, left elbow crutch normal, anatomic cumfy handgrip, closed cuff, aluminium, blue or black	EL7804PALAL	1
Premis EL7804, left elbow crutch normal, anatomic cumfy handgrip, open cuff, aluminium, blue or black	EL7804PCLAL	1
Premis EL7804, right elbow crutch normal, anatomic cumfy handgrip, closed cuff, aluminium, blue or black	EL7804PARAL	1
Premis EL7804, right elbow crutch normal, anatomic cumfy handgrip, open cuff, aluminium, blue or black	EL7804PCRAL	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 12182:1999  
CEN: EN:1985:1998

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

Pagina	2 van 1
Document	ECD.1.2.1 EL7804 Elbow crutch
Procedure- verantwoordelijke	Kwaliteitscoördinator
Revisiedatum	03-01-2020

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The corresponding technical documentation is available to be examined.

This document also applies to the colours blue (BL) and black (ZW). Position 10 and 11 in the article number refers to the colour of the crutches.

**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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