

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

**EC declaration of conformity
EL7804 Elbow crutch**

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

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