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Document	ECD.1.2.1 EL7815 Elbow crutch
Procedure- verantwoordelijke	Kwaliteitscoördinator
Revisiedatum	03-01-2020

**EC declaration of conformity  
EL7815 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:** EL7815  
**Classification:** Class 1 = light risk class

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

	Article No.	Class
Premis EL7815, pair elbow crutches, standard handgrip, closed cuff, Blue	EL7815PAPBL	1
Premis EL7815, pair elbow crutches, standard handgrip, open cuff, Blue	EL7815PCPBL	1
Premis EL7815, single elbow crutch, standard handgrip, closed cuff, Blue	EL7815PASBL	1
Premis EL7815, single elbow crutch, standard handgrip, open cuff, Blue	EL7815PCSBL	1

**Fulfil the relevant requirements of medical devices according to the:**

**EC regulation 93/42/EEC**

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

The corresponding technical documentation is available to be examined.

This document also applies to the colours bronze (BR), black (ZW), red (RO) and Silver (SI). 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



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**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

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2020

