

**EC declaration of conformity  
EL7814 Elbow crutch**

Revisies

| Revisie | Datum<br>(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:** EL7814

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

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

**Udinummer:** 08718874252501, 08718874254604, 08718874254406, 08718874254208,  
08718874254307, 08718874254505, 08718874254802, 08718874252006,  
08718874253201, 08718874253003, 08718874252808, 08718874252907,  
08718874253102, 08718874253409, 08718874252709, 08718874255304,  
08718874255106, 08718874254901, 08718874255007, 08718874255205,  
08718874255502, 08718874252303, 08718874253904, 08718874253706,  
08718874253508, 08718874253607, 08718874253805, 08718874254109

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|---------|------------|----------------|-----------------------------|
| 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 EL7814, pair elbow crutches, standard soft handgrip, closed cuff, Blue | EL7814PAPBL | 1     |
| Premis EL7814, pair elbow crutches, standard soft handgrip, open cuff, Blue   | EL7814PCPBL | 1     |
| Premis EL7814, single elbow crutch, standard soft handgrip, closed cuff, Blue | EL7814PASBL | 1     |
| Premis EL7814, single elbow crutch, standard soft handgrip, open cuff, Blue   | EL7814PCSBL | 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

The corresponding technical documentation is available to be examined.

This document also applies to the colours bronze (BR), red (RO) and Silver (SI). position 10 and 11 in the article number refers to the colour of the crutches

|         |            |                |                             |
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|---------------------------------|----------------------------------|
| Pagina                          | 3 van 1                          |
| Document                        | ECD.1.2.1 EL7814<br>Elbow crutch |
| Procedure-<br>verantwoordelijke | Kwaliteitscoördinator            |
| Revisiedatum                    | 03-01-2020                       |

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Explanation:

**MDR: 2017-745**

Medical device Regulation- Application for Medical Devices

**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

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2023

**Valid Till end of 2024**

|         |            |                |                             |
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