

**EC declaration of conformity  
DE409X – Delta wheeled walker**

**Revisies**

Revisie	Datum (dd-mm-jjjj)	Auteur	Beschrijving van de wijziging
1.0	10-1-2020	R.Keuning	Geïmplementeerd bij Premis

**Manufacturer's name:** Premis Medical BV  
**Business:** De nort 20  
 3931 NG Woudenberg  
 The Netherlands  
**Product:** (DE409X)  
**Classification:** Class 1 = light risk class  
**SRN number:** NL-MF-000005783  
**Udinummer:**

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

	Article No.	Class
3-Wheeled walker Delta red	DE4097AEL	1
3-Wheeled walker Delta red with bag, basket and tray	DE4091AEL	1
3-Wheeled walker Delta red with bag	DE4092AEL	1
3-Wheeled walker Delta red with tray	DE4093AEL	1
3-Wheeled walker Delta red with bag and tray	DE4094AEL	1
3-Wheeled walker Delta red with basket	DE4095AEL	1
3-Wheeled walker Delta red with basket and tray	DE4096AEL	1
3-Wheeled walker Delta Silver (no other colours) with a pressure brake	DE4098CED	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

The corresponding technical documentation is available to be examined.

**This document also applies to the colours blue (B) and silver (S). position 7 in the article number refers to the colour of the wheeled walker**

Versie:	1.0	Classificatie:	Voor Intern gebruik/Publiek
Status:	In gebruik		
Datum:	10-01-2020	Auteur:	R.Keuning

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Document	ECD.1.1.3. DE409X Delta Wheeled walker
Procedure- verantwoordelijk	Kwaliteitscoördinator
Revisiedatum	10-1-2020

## EC declaration of conformity DE409X – Delta wheeled walker

**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 11199-2:2005**

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. 2023

Valid Till end of 2023

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