

EC declaration of conformity Oxygen bottle holders

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: (Oxygen bottle holders)
Classification: Class 1 = light risk class

Confirm solely responsible that the following Medical devices:

	Article No.	Class
RVS Oxygen bottle holders for in the basket of a Provo wheeled walker RO4143	ZU4199	1
RVS Oxygen bottle holders to connect at an oxygen filler device	ZU4199SPEC	1
RVS Oxygen bottle holders for in the cane holder of a Provo wheeled walker RO4143	ZU4199EXTRA	1
RVS Oxygen bottle holders for at the delta wheeled walker DE4097 and a wheelchair	ZU4097	1
RVS Oxygen bottle holders for at a wheeled walker and a wheelchair	ZU409714	1
RVS Oxygen container holders for at a wheeled walker and a wheelchair	ZUAMBUBOX	1
RVS Oxygen container holders for at a wheeled walker and a wheelchair	ZUAMBULOX	1
RVS Oxygen container holders for at a wheeled walker and a wheelchair	ZUVRIJLOX	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

The corresponding technical documentation is available to be examined.

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

**EC declaration of conformity
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Document	ECD.2.3.1 Oxygen bottle holders
Procedure-verantwoordelijk	Kwaliteitscoördinator
Revisiedatum	10-1-2020

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

Dhr. R Keuning



Legally binding signature

Date:

Woudenberg, January 1. 2020

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