EU Declaration of Conformity

Mercado Medic AB
Tryffelslingan 14
SE-181 57 Lidingö, Sweden
EUDAMED SRN: SE-MF-000005191

hereby declare under our sole responsibility as a manufacturer that the product identified in section *1 Product identification* below conform to the provisions of the EU regulations, EC directives, and Swedish national legislations listed in section *2 Regulatory framework* in this document.

1 Product identification

Product name: REAL® 6100 PLUS LiNX

Alternative names: *REAL® 6100 PLUS, REAL® 6100 PLUS EL*

Basic UDI-DI: *732184D0049V*

Risk class (Regulation (EU) 2017/745 Annex VIII): *Class I*

Intended use: *The REAL 6100 PLUS is an electric wheelchair for indoor use designed to be used by people with a reduced ability to walk, but with sufficient physical, cognitive, and perceptive ability to safely drive an electric wheelchair. The device is normally designed to be driven by the user themself but can also be driven by an assistant if the device is equipped with attendant control.*

The REAL® 6100 PLUS is designed and recommended for one or more of the following indications:

- *Inability to walk and severely limited ability to stand.*
- *Limited ability to stand up.*
- *Limited ability to maintain a adequate seating position.*
- *The use of a manual wheelchair is not possible due to disability, but safe use of an electric wheelchair is still possible.*
- *The use of a manual wheelchair is not suitable due to disability and the activities that need to be carried out on a daily basis.*

Known contraindications are cognitive and perceptive disabilities that make it unsuitable to independently drive an electric wheelchair, e.g., severe visual impairment. If the device has been purchased without a prescription from a qualified healthcare professional, the user should consult his/her doctor as to as to whether there are any contraindications.

2 Regulatory framework

The product identified in section *1 Product identification* above conform to the provisions of the EU regulations, EC directives, and Swedish national legislations below:

Regulation (EU) 2017/745 Medical Devices
Regulation (EC) No 1907/2006 Chemical Substances (REACH)
Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)
Directive 2012/19/EU Waste Electrical and Electronic Equipment (WEEE)
Swedish legislation SFS 1993:584
Swedish legislation LVFS 2003:11

No common specifications or harmonised standards are published in the Official Journal of the European Union (OJEU) for Regulation (EU) 2017/745 on Medical Devices (MDR) on the date of issue of this document. The following standards are deemed appropriate and likely to be harmonised with MDR. They have been applied in the design and development of the product as a presumption of conformity.

EN 12184:2014
EN 50581:2012
EN 1041:2008+A1:2013
EN 10993-1:2009
EN ISO 14971:2012

Signed for and on behalf of Mercado Medic AB.

Lidingö, Sweden
Date of issue: 2022-06-08

Andreas Teske
Managing Director