EU & UK Declaration of Conformity

Mercado Medic AB
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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, UK regulations and Swedish national legislations listed in section *2 Regulatory framework* in this document.

1 Product identification

Product name: PROPELLER

Alternative names: -

Basic UDI-DI: 732184D007A3

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

Intended use: *An engine-driven support wheel to be combined with indoor work chairs designed to be used by people who need assistive devices to perform sitting, dynamic activities, move by their own power and/or stand up from sitting. The PROPELLER intends to make it easier for indoor work chair users to move around.*

The PROPELLER is designed and recommended for one or more of the following indications:

- *Difficulty or inability to move around with indoor work chairs.*
- *Pain or exhaustion as a result of everyday tasks at home or at work.*

There are no known contraindications for use of the PROPELLER. If the device is purchased without prescription from qualified healthcare professionals, the user should consult their doctor 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, UK regulations 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
The Medical Devices Regulations 2002 (UK MDR 2002)
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

The following relevant standards were applied in the design and development of the product:

EN 12182:2012
IEC 60601-1-2:2015 clause 4.3, 7 and 8
EN 1041:2008+A1:2013
EN 10993-1:2009
EN ISO 14971:2012
EN 50581:2012
EN ISO 15223-1:2016

Signed for and on behalf of Mercado Medic AB.

Lidingö, Sweden
Date of issue: 2023-04-18

Andreas Teske
Managing Director

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