EU & UK Declaration of Conformity

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

1 Product identification

Product name: REAL® 9200 TWIN

Alternative names: *REAL® 9200 TWIN EL 24V*

Basic UDI-DI: *732184D0029R*

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

Intended use: *The REAL® 9200 TWIN consists of modular indoor work chairs designed to be used by people with obesity who need assistive devices to perform sitting dynamic activities, move by their own power or stand up from sitting. The REAL® 9200 TWIN intends to make use of the user's physical ability and can therefore be adapted individually in a large number of designs. The device is designed to relieve muscles, joints, bones and relieve pains linked to passivity and obesity.*

The REAL® 9200 TWIN is designed and recommended for one or more of the following indications:

- *Difficulty or inability to walk.*
- *Difficulty or inability to stand up from sitting.*
- *Pain or exhaustion as a result of everyday tasks at home or at work.*
- *Where use of a wheelchair is not suitable as a result of activities of daily living.*

There are no known contraindications for use of the REAL® 9200 TWIN. 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

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 12182:2012
IEC 60601-1:2005+A1:2012
EN 1041:2008+A1:2013
EN 10993-1:2009
EN 1335-1:2000

EN 1335-2:2009
EN 1335-3:2009
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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