# EU 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, and Swedish national legislations listed in section *2 Regulatory framework* in this document.

## 1 Product identification

**Product name: REAL® 9000 PLUS**

**Alternative names:** *REAL® 9000 PLUS Series, REAL® 9100 PLUS EL 24V, REAL® 9300 PLUS, REAL® 9400 PLUS EL 24V, REAL® 9700 PLUS, REAL® 9800 PLUS EL 24V, REAL® BASIC Electric, REAL® BASIC Manual, EVI, REAL® 9000 PLUS ARTHRODESE, REAL® 9000 PLUS KIND, REAL® 9000 PLUS KIND EL, REAL® 9000 PLUS EL (AUFSTEHHILFE)*

**Basic UDI-DI:** *732184D0019P*

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

**Intended use:** *The REAL® 9000 PLUS device range consists of modular indoor work chairs designed to be used by people who need assistive devices to perform sitting dynamic activities, move by their own power or stand up from sitting. The REAL® 9000 PLUS 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 also intended to be used by passive users who need to correct their seating position to varying degrees. In these cases, the device is configured to be moved and adjusted by an assistant. The device is designed to relieve muscles, joints, bones and relieve pains linked to passivity.*

*The REAL® 9000 PLUS 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.*
- *Difficulty in maintaining an adequate seating position.*
- *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® 9000 PLUS. 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, 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 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: 2022-06-08

Andreas Teske
Managing Director

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