EU Declaration of Conformity

Mercado Medic AB
Tryffelslingan 14
SE-181 22 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® Standing and Chest support chairs

Alternative names: *REAL® 2000 Series, REAL® 2015, REAL® 2624, REAL® 9500 PLUS, REAL® 9600 PLUS EL 24V*

Basic UDI-DI: *732184D0039T*

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

Intended use: *The REAL 2000 product series, as well as REAL 9500 PLUS and REAL 9600 PLUS EL 24V (Mercado Medic's standing support and chest support chairs below) comprise modular activity chairs intended for indoor use by persons requiring assistive devices to manage dynamic activities that are usually done standing up, when moving by their own effort or for standing up from a seated position. The devices are designed to maximise the user's physical ability, which is why they are individually adaptable and come in a wide variety of versions. The devices are also intended for use by people who have problems with pain and people undergoing rehabilitation for working in a forward-leaning position. In these cases, the device is configured with chest support rather than back support. The devices are designed to relieve pressure on lower limbs, muscles, joints, and bones and to soothe pain caused by passivity.*

Mercado Medic's standing support and chest support chairs are designed and recommended for one or more of the following indications:

- *Difficulty or inability to stand up from sitting.*
- *Difficulty standing up or inability to stand.*
- *Difficulty or inability to walk.*
- *Pain or exhaustion arising from everyday tasks at home or at the workplace that are usually done standing up.*

There are no known contraindications for using Mercado Medic's standing support and chest support chairs. 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: 2021-05-20

Andreas Teske
Managing Director

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