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® 8000 PLUS

Alternative names: *REAL® 8000 PLUS Series, REAL® MEDICAL CLINICS Series, REAL® 8100 PLUS, REAL® 8200 PLUS*

Basic UDI-DI: *732184D0059X*

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

Intended use: *The REAL 8000 product series comprises modular patient seats designed to be used together with primary clinical examination equipment, such as X-ray machines. The device is intended to be used in conjunction with other medical devices in environments and situations that may require adjustable seat positions for different patients to make it possible to conduct the examination efficiently and with satisfactory results. Applicable situations include, but are not limited to, mammography and other X-ray examinations, as well as various kinds of ophthalmological examinations. REAL 8000 is designed to be used wherever a good, seated position is required, such as the following situations:*

- *the patient has to withstand a full examination.*
- *the patient needs support to remain sufficiently motionless in order for the examination method to give satisfactory results.*
- *the patient needs support to remain sufficiently motionless during a biopsy, for example.*
- *being able to carry out a more efficient examination in order to reduce the time during which the patient needs to endure an emotional strain, as can be experienced in mammography, for example.*

The REAL 8000 product series is designed to be operated by a professional who ensures an appropriate adjustment in relation to both the patient and the primary examination equipment.

There are no known contraindications for using the REAL 8000 product series.

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 ISO 21856:2022
IEC 60601-1:2005 + A1 +A2
EN 20417:2021
EN 10993-1:2009
EN 1335-1:2000

EN 1335-2:2018
EN ISO 14971:2020/A11:2021
EN 50581:2012
EN ISO 15223-1:2021

Signed for and on behalf of Mercado Medic AB.

Lidingö, Sweden
Date of issue: 2023-09-21

Andreas Teske
Managing Director

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