EU Declaration of Conformity

Mercado Medic AB
Tryffelslingan 14
SE-181 22 Lidingö, Sweden

hereby declare under our sole responsibility as a manufacturer that the product identified below,

Product name: REAL 9000[1]
Intended use: *For users with disablement relating to neck, back, legs and/or arms.*

conform to the provisions of the following EC directives, regulations and national legislations:

Directive 93/42/EEC Medical Devices
Directive 2006/42/EC Machinery
Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)
Directive 2012/19/EU Waste Electrical and Electronic Equipment (WEEE)
Regulation (EC) No 1907/2006 Chemical Substances (REACH)
Swedish legislation SFS 1993:584
Swedish legislation LVFS 2003:11

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

EN 12182:2012
EN 50581:2012
EN 1041:2008+A1:2013
EN 10993-1:2009
EN ISO 13857:2008
EN ISO 15223-1:2016

EN ISO 14971:2012
EN 349+A1:2008
EN 614-1:2006+A1:2009

Signed for and on behalf of Mercado Medic AB.

Lidingö, Sweden
Date of issue: 2020-02-27

Martin Bonnevier Kronlid
R&D and Program Manager

[1] Alternative product names: REAL 9000, REAL 9000 CHILD EL, REAL 9000 CHILD, REAL 9000 EL COXIT, REAL 9000 EL, REAL 9000 PLUS CHILD, REAL 9000 PLUS EL CHILD, REAL 9000 PLUS EL COXIT, REAL 9000 PLUS EL, REAL 9000 PLUS MANUAL ADULT, REAL 9000 PLUS, REAL 9100 PLUS EL ADULT, REAL 9100, REAL 9100 PLUS, REAL 9300 CHILD, REAL 9300 PLUS CHILD, REAL 9300 PLUS MANUAL CHILD, REAL 9400 CHILD, REAL 9400 PLUS CHILD, REAL 9400 PLUS EL CHILD, REAL 9500 PLUS, REAL 9500, REAL 9600 EL, REAL 9600 PLUS EL, REAL 9700 COXIT, REAL 9700 PLUS COXIT, REAL 9700 PLUS MANUAL COXIT, REAL 9800 EL COXIT, or REAL 9800 PLUS EL COXIT.