

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 6100 PLUS

Intended use: *Powered wheelchair for indoor use, for users with severe disablement relating to neck, back, legs and/or arms.*

Alternative names: REAL® 6100 PLUS, 6100 PLUS LINX

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 12184:2014
EN 50581:2012
EN 1041:2008+A1:2013
EN 10993-1:2009

EN ISO 13857:2008
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
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Martin Bonnevier Kronlid
R&D and Program Manager