

# 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: EVI**

Intended use: *Paediatric chair for young 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**  
**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 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**

Signed for and on behalf of Mercado Medic AB.

Lidingö, Sweden  
Date of issue: 2019-12-19



Martin Bonnevier  
R&D and Program Manager