



EU Declaration of Conformity

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Manufacturer Abilia AB
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Product Single Registration Number SE-MF-000005211
Name: MEMO Dayboard
Part No: 508820, 508825, 508830
Risk class: I
Basic UDI-DI 734002311BOARDVS

Intended use/purpose MEMO Dayboard is a planning board that is intended to support persons who need a visual overview of the day in relation to the passage of time.

Directive(s)/Regulation(s)

MDR 2017/745/EU	European Medical Device Regulation
2014/30/EU	EMC directive
2011/65/EU	RoHS Restriction of hazardous substances directive
1907/2006/EC	REACH, the product does not include at all or less than 0,1% of chemicals in the candidate list "Substances of Very High Concern"

Standards used

EN 55022:2010	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement
EN12182:2012	Assistive products for persons with disability - General requirements and test methods
EN 60601-1:2006+A11:2011+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment Part1-2 General requirements for basic safety and essential performance electromagnetic disturbances requirements and tests
ISO21801-1:2020	Cognitive accessibility – Part 1: General guidelines
ISO 21802:2019	Assistive products – Guidelines on cognitive accessibility – Daily time management

We declare under our sole responsibility that the product, to which this declaration relates, are in conformity with the above directive(s) and regulation(s).

Solna, 2021may28

Anna Wik, Manager Quality, Sustainability and Regulatory Affairs Abilia AB