



# EC/EEA Declaration of Conformity

Doc. ID: 22712

<b>Manufacturer</b>	Abilia AB Råsundavägen 6 SE-169 67 Solna SWEDEN Phone: +46 8 594 694 00	
<b>Product</b>	Name:	MEMOplanner Large
	Part No:	462880
	Risk class:	I
<b>Intended use/purpose</b>	MEMOplanner is a digital calendar that is intended for persons who require extended cognitive support regarding time, structure, planning and graphic clarity.	
<b>Directive(s)/Regulation(s)</b>		
MDR 2017/745/EU	European Medical Device Regulation	
2014/30/EU	EMC directive	
2011/65/EU	RoHS Restriction of hazardous substances directive	
<b>Standards used</b>		
EN 12182:2012	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	
EN55024:2010+A1:2015	Information technology equipment. Immunity characteristics. Limits and methods of measurement	
EN 55032:2015	Electromagnetic compatibility of multimedia equipment. Emission Requirements	
EN 55035:2017	Electromagnetic compatibility of multimedia equipment - Immunity requirements	
EN 61000-3-2:2014	Electromagnetic compatibility (EMC) -- Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16A per phase)	
EN 61000-3-3:2013	Electromagnetic compatibility (EMC) -- Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <=16A per phase and not subject to conditional connection	

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, 2021may10

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