



ABILIA

EU Declaration of Conformity

Doc. ID: 24870-1

Manufacturer

Abilia AB
Råsundavägen 6
SE-169 67 Solna
SWEDEN
Phone: +46 8 594 694 00
Single Registration Number SE-MF-000005211

Product

Name: MEMOplanner Medium
Part No: 462890
Risk class: I
Basic UDI-DI 734002311PLAN59

Intended use/purpose

MEMOplanner is a digital calendar that is intended for persons who require extended cognitive support regarding time, structure, planning and graphic clarity.

Directive(s)/Regulation(s)

MDR 2017/745/EU	European Medical Device Regulation
2014/30/EU	EMC directive
2011/65/EU and 2015/863/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 12182:2012	Assistive products for persons with disability – General requirements and test methods
EN 62368-1:2014	Audio/video, information and communication technology equipment – Part 1: Safety requirements
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance: Electromagnetic disturbances
EN 55032:2015 + A11:2020	Electromagnetic compatibility of multimedia equipment. Emission Requirements
EN 55035:2017 + A11:2020	Electromagnetic compatibility of multimedia equipment – Immunity requirements
EN 61000-3-2:2019	Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current \leq 16A per phase)

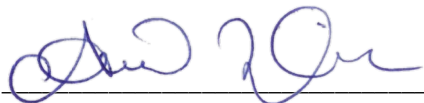
Standards used

EN 61000-3-3:2013+
A1:2019

Electromagnetic compatibility (EMC) -- Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems (equipment rated current ≤ 16 A per phase)

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, 2022feb21



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