

## **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:

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 + Electromagnetic compatibility of multimedia equipment. Emission

A11:2020 Requirements

EN 55035:2017 + Electromagnetic compatibility of multimedia equipment - Immunity

A11:2020 requirements

EN 61000-3-2:2019 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for

harmonic current emissions (equipment input current <= 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 <=16A 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