



ABILIA

EU Declaration of Conformity

Doc. ID: 24584

Manufacturer

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Single Registration Number SE-MF-000005211

Product

Name: CARY
Part No: 508900
508910
508930
Risk class: I
Basic UDI-DI 734002311CARY2Y

Intended use/purpose

CARY Base is a calendar clock that is intended to provide support for persons who have deficiencies in time orientation and memory. CARY Base is intended for indoor use in a home environment.

Directive(s)/Regulation(s)

MDR 2017/745/EU	European Medical Device Regulation
2014/30/EU	EMC directive
2014/53/EU	Radio Equipment 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"

Main standards used

SS-EN ISO 21856:2022	Assistive products - General requirements and test methods
IEC 60601-1: 2005 + A1: 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 + A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance electromagnetic disturbances requirements and tests
EN 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 300328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band;

EN 301 893 V2.1.1	Harmonised Standard for access to radio spectrum 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 300 440 V2.1.1	Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 50665:2017	Generic standard for assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
ISO 21801-1:2020	Cognitive accessibility -- Part 1: General guidelines
SS-EN ISO 21802:2021	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, 2023 December 18



Peter Löwendahl, PRRC, Abilia AB