

EU Declaration of Conformity

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Manufacturer Abilia AB

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SWEDEN

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Single Registration Number SE-MF-000005211

Product Name: MEMO Timer

Part No: 500150, 500155, 500160, 500165

Risk class:

Basic UDI-DI 734002311TIME68

Intended use/purpose MEMO Timer is a visual timer that is intended to support persons to

understand the length and passage of time.

Directive(s)/Regulation(s)

MDR 2017/745/EU European Medical Device Regulation

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

EN12182:2012 Assistive products for persons with disability - General

requirements and test methods

EN 60601-1-2:2015 Medical electrical equipment Part1-2 General requirements for

basic safety and essential performance electromagnetic

disturbances requirements and tests

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, 2021 may 28

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