



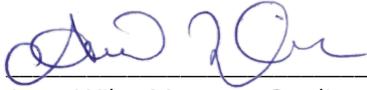
EU Declaration of Conformity

Doc. ID: 23635-2

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|-----------------------------------|---|
| Manufacturer | Abilia AB Råsundavägen 6 SE-169 67 Solna SWEDEN Phone: +46 8 594 694 00 |
| | Single Registration Number SE-MF-000005211 |
| Product | Name: Lightwriter SL50 Part No: 1740000, 1740100, 1740200, 1740300, 1740400 Risk class: Class I Basic UDI-DI 734002311LIGHTYW |
| Intended use/purpose | <p>Lightwriter SL50 is a portable, dedicated text-to-speech communication device for literate users who are unable to communicate effectively through speech. It enables face-to-face communication as well SMS communication and mobile phone communication.</p> <p>Lightwriter SL50 can be used at home, in school, at the workplace or on the move. The product is intended for indoor use, and with the keyboard cover applied, outdoor use is also possible.</p> |
| Directive(s)/Regulation(s) | MDR 2017/745 Medical device regulation 2014/30/EU EMC directive 2011/65/EU and RoHS Restriction of hazardous substances directive 2015/863/EU 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 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic +A11:2011+A1:2013 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 EN12182:2012 Assistive products for persons with disability - General requirements and test methods |

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, 2021may28



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