

Process Abilia / Forskning och Utveckling / Dokumentation  
Godkänt datum 2019-03-21 (Cecilia Arthuis)  
Ändrat datum 2019-03-21 (Cecilia Arthuis)  
Giltighetsområde

Dokumentkategori  
Siste revision  
Nästa revisionsdatum

## EC/EEA Declaration of Conformity

**Manufacturer**

Abilia AB  
Råsundavägen 6  
SE-169 67 Solna  
SWEDEN  
Phone: +46 8 594 694 00

**Product**

Name: Lightwriter SL50  
Model / Type: Lightwriter SL50

**Directive(s)/Regulation(s)**

MDD 93/42/EEC (Class 1) Medical devices directive  
RoHS2 2011/65/EU Restriction of hazardous substances directive  
REACH 1907/2006/EC Registration, evaluation, authorisation and restriction of chemicals regulation

**Standards used**

EN 12182:2012 Assistive products for persons with disability  
EN 14971:2012 Medical devices – Application of risk management to medical devices  
EN 60601-1-2:2015, ed. 4 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: 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, March 21, 2019



Cecilia Arthuis, Director of Product Management and R&D Abilia AB