

Process	Abilia / Forskning och Utveckling / Dokumentation	Dokumentkategori
Godkänt datum	2019-03-21 (Cecilia Arthuis)	Siste revision
Ändrat datum	2019-03-21 (Cecilia Arthuis)	Nästa revisionsdatum
Giltighetsområde		

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