## EC/EEA Declaration of Conformity

In accordance with ISO/IEC 17050-1

Manufacturer

Abilia AB

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Phone: +46 8594 694 00

**Product description** 

Name:

**Emfit Epilepsilarm** 

Model / Type:

Laddningsbar kontrollenhet + sensor

Adapterkabel Batterieliminator

Kabel till sjukhuslarm 6.3 mm

Directive(s)

MDD 93/42/EEC Class 1

EMC 2004/108/EG LVD 2006/95/EG RoHS2 2011/65/EU

Standards used

EN 12182:2012

Assistive products for persons with

disability

EN 60950-1

Information technology equipment -

Safety - Part 1: General requirements

EN 14971:2000

Medical devices – Application of risk

management to medical devices

EN 55022:2010

Information technology equipment - Radio disturbance characteristics -

Limits and methods of measurement

EN 55024:2010

Information technology equipment.

Immunity characteristics. Limits and

methods of measurement

We declare under our sole responsibility that the product(s), to which this declaration relates, are in conformity with the above directive(s).

The declaration covers CE marked equipment/devices manufactured from the period commencing September 8<sup>th</sup> 2017 and until such time a renewed conformity declaration is raised.

Gothenburg, September 8, 2017

Pontus Berglund, R&D Manager Abilia AB