EU Declaration of Conformity

Doc. ID: 23818-2

Manufacturer	Abilia AB Råsundavägen 6 SE-169 67 Solna SWEDEN Phone: +46 8 594 694 00	
	Single Registration Number	SE-MF-000005211
Product	Name:	Emfit epilepsy alarm
	Part No:	464000 464031 464040 464050 464052
	Risk class:	I
	Basic UDI-DI	734002311EPIL44

Intended use/purpose

The product is intended to be used to assist in sensory monitoring and to notify the caregiver of the body movements of a person lying on a mattress equipped with the under-mattress sensor due to a tonic-clonic seizure while sleeping and of the presence of the monitored person on the mattress equipped with the under-mattress bed sensor and if he or she gets up from the mattress.

Directive(s)/Regulation(s)

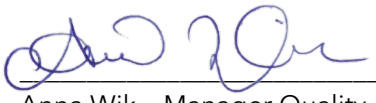
MDR 2017/745/EU	European Medical Device Regulation
2014/30/EU	EMC directive
2011/65/EU and 2015/863/EU	RoHS Restriction of hazardous substances directive
1907/2006/EC	REACH The product does not include at all or less than 0,1% of chemicals in the candidate list "Substances of Very High Concern"

Standards used

EN 60601-1:2005 +A1:2013	Medical electrical equipment - Part 1: General requirements for basic 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

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