EC Declaration of Conformity

Manufacturer:

iTs Designs Ltd
Atherstone House
Merry Lees Industrial Estate
Desford
Leicestershire LE3 3LR
England

Issue Date	19/11/2008	Updated 10/12/16
Device(s)	P154AA P154AB P154AC	Bed movement monitor with sound transient, radio Bed movement monitor with incontinence, radio Bed movement monitor with sound level, radio
Accessories	P114 P158 P126 P141B P142A P142E P143C P143G P144C P145 P113x P171 P159	Bed Movement Sensor Microphone NiMH Battery, Size PP3, 9v Cable for Moisture Sheet Moisture sensing sheet (Instant) Moisture sensing sheet (Absorbent) Bed Mat Occupancy Sensor Bed Ribbon Occupancy Sensor Bed Leg Occupancy Sensor Range of Nurse Call connection leads Range of power supplies for P154AB, P154BB Range of power supplies for P154AA, P154AB Bed/Wall Mounting Bracket
Description	The P154 models cover a range of small monitors that detect abnormal conditions occurring in a bed that might indicate an Epilepsy Episode. These cover bed movement, bed wetting, sounds and bed vacation. The alarms are transmitted by Safelink Radio or to a connected Nurse Call or Telecare system	
Directives	**93/42/EEC** **2014/53/EU** 2011/65/EU	Medical Devices Directive RTT&E Directive Permitted Materials (UK)
Classification	Medical Device Class 1	
	Safety Class II	
Standards Applied	EN 14971:2012 EN 60601-1:2006+A12:2014 EN 60601-1-2:2015 EN 60601-1-8:2010+A1:2015 EN62366:2015 EN55011:2016 EN 12182:2012 EN 300 220-1 V2.4.1(2012-05)	Risk Assessment Medical Device General Requirements Medical Device EMC Medical Device Alarm Systems Product Usability Engineering ISM Radio Disturbance Technical Aids for Disabled Persons Radio Transmissions: Short Range Devices

Declaration:
We certify that the apparatus to which this declaration relates conforms with the relevant requirements set out in the above referenced EC Directive(s) and standards
Signatory:

D Godfrey BSc(Hons) FIEE Ceng
Managing Director