

EU Declaration of Conformity

Manufacturer:

iTs Designs Ltd
 (Alert-iT Care Alarms)
 Atherstone House
 Merry Lees Industrial Estate,
 Desford, Leicestershire,
 LE9 9FE, England



Issue Date	14/June/2007	Updated 10/Dec/2016
Device(s)	P139BA	Bed Monitor, radio.
Accessories	P140 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 P139 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 (gross & shallow), 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 2012/19/EU	Medical Device Directive (MDD) Radio Equipment Directive (RED) Permitted Materials (RoHS2) Waste Electrical and Electronic Equipment Directive (WEEE)
Classification	Medical Device: Class 1 Safety: Class II	
QMS	ISO 13485	Medical Devices Quality System
Standards Applied	EN 14971:2012 EN 60601-1:2006+A12:2014 EN 60601-1-2:2015 EN 60601-1-8:2010+A1:2015 EN 62366-1:2015 EN 55011:2016 EN 12182:2012 EN 300-220-2 V2.4.1 (2012-05)	Risk Assessment Medical Device General Requirements Medical Device EMC Medical Device Alarm Systems Medical Devices applications of usability ISM Radio Disturbance Limits Technical Aids for Disabled Persons Permitted radio transmission: 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