

EC Declaration of Conformity



Manufacturer:

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

Issue Date	14/9/2011	updated 19/12/16
Device(s)	P166A	Radio Guide Light Monitor
Accessories	P143C P143G P144C P171 P159B P145 Miscellaneous switch devices	Bed Mat Occupancy Sensor Bed Ribbon Occupancy Sensor Bed Leg Occupancy Sensor Range of power supplies Bed/Wall Mounting Bracket Range of Nurse Call Leads Passive switching devices covered by EN12182
Description	The P166 models cover a range of small monitors that detect a user leaving a bed and provides a reassuring guide light for safety. An alarm can be transmitted either instantly or after a programmed. The alarms are transmitted by Safelink Radio (version A) or to a connected Nurse Call or Telecare system (version B)	
Directives	2014/53/EU 2011/65/EU	RTT&E Directive Permitted Materials (UK)
Classification	Safety Class II	
Standards Applied	EN 14971:2012 EN 60950-1:2006+A2:2013 EN 60601-1-2:2015 EN 60601-1-8:2007+A1:2013 EN 55011:2016 EN 12182:2012 EN 300 220-1 V2.4.1(2012-05)	Risk Assessment Safety Medical Device EMC Medical Device Alarms ISM Radio Disturbance Assistive Technology 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