

# EC Declaration of Conformity



**Manufacturer:**

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

<b>Issue Date</b>	08/Feb/2007	Updated 20/Dec/2016
<b>Device(s)</b>	P137B P137C	64 Channel Professional Safelink Pager 8 Channel Professional Safelink Pager
<b>Accessories</b>	P153 P146	Power supply for pager USB Docking Station
<b>Description</b>	The P137 Pagers uses the Safelink protocol to display the status of a range of monitors that are used in domestic and professional care settings. They form an accessory to these monitors to form system compliant with the Medical Devices Directive 93/42/EEC.	
<b>Directives</b>	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)
<b>Classification</b>	Medical Device: Class 1	
<b>QMS</b>	ISO 13485	Medical Devices Quality System
<b>Standards Applied</b>	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) ISO 22196:2011	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 Anti-microbial treatment

**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