

EC Declaration of Conformity




Manufacturer:

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

Issue Date	8/2/2007	Update 20/12/16
Device(s)	P137B P137C	64 Channel Professional Safelink Pager 8 Channel Professional Safelink Pager
Accessories	P153 P146	Power supply for pager USB Docking Station
Description	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	
Directives	93/42/EEC 2014/53/EU 2011/65/EU	Medical Device RTT&E Permitted Materials
Classification	Class 1 Medical	
Standards Applied	EN 14971:2012 EN 60601-1:2006+A12:2014 EN 60601-1-2:2015 EN 60601-1-8:2007+A1:2013 EN 62366:2015 EN 55011:2016 EN 12182:2012 ISO22196:2011 EN 300 220-1 V2.4.1(2012-05)	Risk Assessment Medical Device General Requirements Medical Device EMC Medical Alarm Systems Medical Device Usability ISM Radio Disturbance Technical Aids for Disabled Persons Anti-microbial treatment 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