For Product Family	Alert-iT Pager (Non-Medical)
Legal Manufacturer; Name and Address	iTs Designs Ltd., (Trading as: Alert-IT Care Alarms) Fernie House (Unit 3) Coalville Business Park Coalville, Leicestershire LE67 3NR UK
Trade Name or Registered Trade Mark	P201 -Alert-iT Pager (Non-Medical)
Product Codes & Labelling Descriptions	As per ANNEX A
Harmonised Standards, or Common Specifications Applied	As per ANNEX B

Statement of Undertaking:

The undersigned declares that the EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, and that the device(s) listed within are in conformity with the Low Voltage Directive (2014/35/EU), EMC Directive (2014/30/EU), Radio Equipment Directive (2014/53/EU), 2012/19 EU WEEE Directive and 2011/65/EU Restriction of Hazardous Substances.

	Name	Title / Function	Location	Date	Signature
Signed by:	Rick Gunn	Operations Director	iTs Designs Ltd., (Trading as: Alert-IT Care Alarms)	30th April 2025.	
On behalf of	iTs Designs Ltd., (Trading as: Alert-IT Care Alarms) Fernie House (Unit 3) Coalville Business Park Coalville Leicestershire LE67 3NR UK				

Annex A – Associated Model Identities

Product Code	Labelling Description
P201AAA	Standard 4 Channel MD Pager (434 MHz)
P201BAA	Advanced 128 Channel MD Pager (434 MHz)
P201ABA	Standard 4 Channel MD Pager (869 MHz)
P201BBA	Advanced 128 Channel MD Pager (869 MHz)

Annex B – Harmonised Standards or Common Specifications Applied

Harmonised Standard or Common Specification	Description
Note that whilst **the P201 Alert-iT Pager (Non-Medical) is not a medical device**, the product has been designed, manufactured and tested in accordance with the following standards applicable to medical devices. Seperate testing to non-medical standards has not been performed as the requirements are less stringent than those for medical devices.	
EN ISO 14971:2019	Application of Risk management to medical devices.
EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
EN 62304:2006	Medical device software - Software life-cycle processes
EN ISO 62366-1:2015	Medical devices. Application of usability engineering to medical devices
EN 60601-1:2006/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1: 2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-8:2007+A2:2021	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-11:2015+A1:2021	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 62133-1:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary62 cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer

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