For Medical Device / Device Family (Generic Device Group)	Alert-iT Pager
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	P202 - Alert-iT Pager
Legal Manufacturer Single Registration Number (SRN)	GB-MF-000027859
EU Authorised Representative; Name and Address	LEISNER ApS Korsvangcentret DK-5610 Assens Denmark
EU Authorised Representative Single Registration Number (SRN)	DK-AR-000027183
Basic UDI-DI for device/device family	As per ANNEX A
Product Codes & Labelling Descriptions	As per ANNEX A
Device Classification; as per Annex VIII of the MDR 2017/745	Class 1 Non-sterile, Non-measuring, Non-reusable surgical instrument, Non-custom made. Rule 13
Intended Use	The Alert-iT Pager is intended to assist in caregiving by notifying the carer to attend the patient in order the verify their wellbeing
Harmonised Standards, or Common Specifications Applied	As per ANNEX A
Medical Device Regulation Conformity Assessment Procedure Undertaken	Manufacturer self-certification through issuance of an EU Declaration of Conformity in accordance with Article 19 of the Medical Device Regulation, having acted in accordance with the technical documentation requirements of Annexes II and III, as detailed in Article 52 (Point 7).

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 EU Medical Device Regulation; (EU) 2017/745

	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
P202AAA	Standard 4 Channel MD Pager (434 MHz)
P202BAA	Advanced 128 Channel MD Pager (434 MHz)
P202ABA	Standard 4 Channel MD Pager (869 MHz)
P202BBA	Advanced 128 Channel MD Pager (869 MHz)

Annex B – Harmonised Standards or Common Specifications Applied

Harmonised Standard or Common Specification	Description
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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