EU Declaration of Conformity

Manufacturer:

iTs Designs Ltd.
(T/A: Alert-iT Care Alarms)
Fernie House (Unit 3)
Coalville Business Park
Coalville, Leicestershire
LE67 3NR, England
Tel: +44 (0) 1530 239 900
Single Registration Number (SRN): GB-MF-000027859

European Authorised Representative:

LEISNER ApS
Korsvangcentret
DK-5610 Assens
Denmark
Tel: +45 6371 3050
Single Registration Number (SRN): DK-AR-000027183

Description:	This "P176B Reset Button" is an accessory to the "Companion Mini Pro" and is used to reset alarms. The device sends the alarm reset notifications via Alert-iT's Safelink™ radio protocol.	
Directives:	2017/745	Medical Device Regulation (MDR)
	2014/53/EU	Radio Equipment Directive (RED)
	2011/65/EU + 2015/863	Permitted Materials (RoHS)
	2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
Standards Applied:	BS EN 60601-1:2006+A12:2014	Medical Equipment: Basic Safety Requirements
	BS EN 60601-1-2:2015+A1:2021	Medical Equipment: EMC Requirements
	BS EN 60601-1-6:2010+A1:2015	Medical Equipment: Usability Requirements
	BS EN 60601-1-8:2007+A11:2017	Medical Equipment: Alarm Systems
	BS EN 60601-1-11:2015	Medical Equipment: Home Healthcare Requirements
	EN 300-220-2 v3.1.1	Radio Emissions (434 MHz Band)
	EN 300-220-3-1 v2.1.1	Radio Emissions (869 MHz Band)

Models covered by this certificate:

Model:	Description:	Basic UDI-DI (GMN):	UDI-DI (GTIN-14):
P176BAA	Reset Button: 434 MHz, Branding	506053070P176BS8	5060530701117
P176BBA	Reset Button: 869 MHz, Branding	506053070P176BS8	5060530701124
P176BAB	Reset Button: 434 MHz, Branding	506053070P176BS8	5060530701131
P176BBB	Reset Button: 869 MHz, Branding	506053070P176BS8	5060530701148
P176BAC	Reset Button: 434 MHz, Branding	506053070P176BS8	5060530701155
P176BBC	Reset Button: 869 MHz, Branding	506053070P176BS8	5060530701162

We hereby, under our sole responsibility declare, that the product listed above, is in conformity with the Medical Device Regulation (MDR) 2017/745 as a Class 1 medical device accessory based on Rule 13 of Annex 8 and the relevant European harmonised standards listed above.

The product concerned has been manufactured under a quality management system (ISO 13485:2016) according to Annex 9 of MDR 2017/745 EU.

This EU declaration of conformity was written accordance to Annex 4 of the MDR, and all supporting documentation is retained at the premises of the manufacturer.

Signed:

Date: 20/June/2024 Place: Leicester, UK. Name: Rick Gunn Position: Director