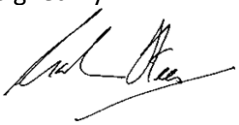
UK, USA & EU DECLARATION OF CONFORMITY

Under our Sole Responsibility we declare that the Medical Device (Prevasse & Alerta Pressure Relieving Cushion) is Class I, non-sterile multi use and is in accordance with the Classification Rules (Rule 1) and in conformity with the General Safety & Performance Requirements and provisions of the EU Medical Device Regulations 2017/745 (Annex IV) and are subject to the procedures set out in Article 19 in that Regulation, along with the UK Medical Devices Regulations 2002 as amended by UK Medicines & Medical Devices Act 2021 (Chapter 3). They are manufactured in accordance with the Procedures and Policies contained in our Quality Management System, which has been registered with International Associates Ltd against the international Standard ISO 13485:2016,); along with the USA Code of Federal Regulations Title 21.

Basic UDI DI:	506018217ACALT2034Y
EU Authorised Representative:	PJ Dahlhausen & Co GmbH, Emil-Hoffmann-Straße 53, 50996 Köln, Germany.
CND Code:	033303 (Patient Alleviation Cushion)
GMDN Code:	47477 (Air Filled Chair Cushion)
EMDN Code:	V080301 (Anti-Decubitus Medical Cushion)
MDN Code:	1214 (Devices used in Healthcare)
MDT Code:	2002 (Devices using Plastic Technologies)
UNSPSC:	25174602 (Seat Cushions)
NBOG Number:	MD0100
UMDNS Code:	11093 (Cushions)
ISO 13485 Certificate Number:	01-0130-1-MED
UKAS Number:	10093
Alerta Trade Mark Registration:	EU012798955
Product Codes:	PRE100 – Prevasse; ALT-203 - Alerta
Bar Code:	5060182171474 – for 1 5060182171481 – Pack of 5
MHRA Registration:	CA016211
DUNS ID Number:	22-183-6112
Company Registration:	04201958
CFR:	890.3175

Signed By



Graham Steer
Management Representative Date: 29th July 2022