# EU Declaration of Conformity

**Statement of Use: Verify status before each use**

This declaration is issued under the sole responsibility of Alerta Medical Ltd.

We, the manufacturer, hereby declare that the below-mentioned medical device is designed and manufactured by Alerta Medical Ltd. in accordance with the scope of a quality system which meets the requirements of the European Communities' Council Regulation 2017/745/EC in accordance with Annex I, General Safety and Performance Requirements and Annex IX.

All supporting documentation is retained at the premises of the manufacturer.

| | | | | | |
|---|---|---|---|---|---|
| **Legal Manufacturer** | Alerta Medical Ltd. | | | | |
| **Legal Manufacturer Address** | 4 Symington Place, Riverside Business Park, Irvine, KA11 5DE, UK. | | | | |
| **SRN (Single Registration Number)** | GB-MF-000013708 | | | | |
| **Product Family** | Alerta Alternating Air System | | | | |
| **Product/Trade Name** | Reference Schedule | | | | |
| **Product Code** | Reference Schedule | | | | |
| **Intended Purpose** | The mattress design provides effective comfort, care and pressure redistribution and relief for patients in hospital, nursing and care home environments.<br>• To help and reduce the incidence of pressure ulcers while optimizing patient comfort.<br>• For long term care of patients suffering from or at risk of pressure ulcers.<br>• For pain management as prescribed by a physician. | | | | |
| **Basic UDI-DI** | 506061453AltMattSys4C | | | | |
| **GMDN Code** | 63241 - Alternating pressure bed mattress system<br>47478 – Alternating pressure bed mattress overlay system | **EMDN Code** | V08068099 – Medical Beds (other accessories) | **CND Code** | Y033306 – Pressure Alleviation Mattresses and Underpads. |
| **Risk Classification –**<br>**(according to Annex VIII of regulation 2017/745)** | Class I | | Rule 12 | | |

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| **Sterilisation Method** | Non-sterile | |
| **Conformity Assessment** | Article 52, section 7 of the Medical Device Regulation 2017/745/EC<br>Technical Documentation: Annex II and Annex III of regulation 2017/745 | |
| **Common Specifications** | None | |
| **Standards** | • BS EN ISO 13485+A11:2021<br>• BS EN ISO 9001:2015<br>• BS EN ISO 20417:2021<br>• BS EN ISO 10993-1:2020<br>• BS EN ISO 15223-1:2021<br>• BS EN ISO 14971:2019/A11:2021 | |
| **Authorised Representative** | CS Lifesciences Europe Limited<br><br>Email: eurep@cslifesciences.com | The Black Church,<br>St Mary's Place, Dublin 7<br>Dublin<br>D07 P4AX<br>Ireland |
| | **SRN (Single Registration Number)** | |
| | IE-AR-000004113 | |
| **Notified Body for CE Mark** | Not Applicable | Not Applicable |
| **EC Certificate for CE Mark** | Not Applicable | Not Applicable |
| **Quality System Certificate** | Alerta Medical declares that its products are designed and manufactured in accordance with the scope of a quality system which meets the requirements of Article 10 of the Medical Device Regulation EU 2017/745. | |

Approved on behalf of Alerta Medical Ltd.

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| **Ian Lindberg**<br>**CEO** |  |
| **Date, town, and country of signing** | **22nd October 2024, Irvine, United Kingdom** |

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**Schedule: Product Codes/ Catalogue Numbers**

| Product Code/ Catalogue Number | Product Name |
|---|---|
| ALT-9001 | Alerta Bubble 2 Mattress System |
| ALT-9004 | Alerta Pearl Air Mattress System |
| ALT-9005 | Alerta Emerald 2 Air Mattress System |
| ALT-9007 | Alerta Sapphire 2 Replacement System |
| ALT-9006 | Alerta Emerald Auto Air Mattress System |
| ALT-9008 | Alerta Ruby 2 Replacement System |
| ALT-9009 | Alerta Ruby Auto Replacement System |
| ALT-9300 | Alerta Bariatric 2 Replacement System |
| ALT-213/02 | Alerta Partner Cushion System |
| ALT-215 | Alerta Mobile Cushion System |
| ALT-HYB2/05 | Alerta Hybrid air Mattress System |