EC Declaration of Conformity

Declaration Number: **DC - 2**

Manufacturer: **Alerta Medical, 4 Symington Place, Riverside Bus. Pk, Irvine, KA11 5DE UK**

EU Authorised Rep: **CS Lifesciences Europe Limited, 3 Inns Quay, Dublin 7, Ireland, D07PW4F**

Product Family Name: **Fall Prevention Devices and Accessories**

Product Name/Codes: **See schedule**

Product Name	Product Code
Bed Alertamat System	BAM
Bed Alertamat System - Wireless	W-BAM
Chair Alertamat System	CAM
Chair Alertamat System - Wireless	W-CAM
Floor+ Alertamat System	PAM
Floor+ Alertamat System - Wireless	W-PAM
Deluxe Alertamat System	DAM
Deluxe Alertamat System - Wireless	W-DAM
Alerta Detect Motion Sensor	ALT-DET
Alerta Wireless Nurse Call Button	W-NCB
Alerta Wall Point Receiver	W-WPR
Alerta Wireless Transmitter	W-FBCT

CE

Classification (MDD, Annex IX) and Rule Number: **Class I, Annex IX, Rule Number 12**

Declaration

Alerta Medical hereby declares that the devices specified above conforms with the Annex 1 - Essential Requirements of the Medical Device Directive - 93/42/EEC of June 14, 1993 as amended by Directive 2007/47/EC of 5 September 2007.

The stated products are designed and manufactured by Alerta Medical, in accordance with the scope of a quality system which meets the requirements of the Medical Devices Directive - 93/42/EEC of June 14, 1993 as amended by Directive 2007/47/EC of 5 September 2007

Alerta Medical declare that our products are compliant with RoHS 2 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

To ensure conformity with the provisions of the Directive applicable to Class I equipment, Alerta Medical has designed and manufactured the device specified above in accordance with:

- **BS EN 60601-1-2:2007 Medical Electrical Equipment. General Requirements for basic safety and essential performance**

This Declaration of Conformity is issued under the sole responsibility of the manufacturer

Authorised By:

Ian Lindberg
Managing Director

1st January 2021