EC Declaration of Conformity

Declaration Number: **DC - 2**

Manufacturer: **Alerta Medical**

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

Product Name/Codes: **See schedule**

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

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
Chief Executive Officer

29th October 2018

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