

## Declaration of Conformity to:

**Medical Device Directive 93/42/EEC as amended 2007/47/EC  
and the R&TTE Directive 1999/5/EC**

### **For Epilepsy Monitors MP2, MP5, MP6 and ST2**

This is to certify that the class IIa equipment specified above conforms to the above Directives as transposed in to national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:

- A Technical File compliant to 93/42/EEC Annex VII
- Compliance to the Essential Requirements as per 93/42/EEC Annex I
- Compliance to 93/42/EEC Annex V Production Quality Assurance
- Quality Assurance procedures in accordance with BS EN ISO13485:2003

The CE marking of product being subject to the achievement and maintenance of certification to 93/42/EEC Annex V by BSi, Notified Body 0086, Certificate number CE 80927.

Based on assessment of compliance to:

BS EN 60601-1 Electrical Safety for Medical Devices  
BS EN 60601-1-1 Electrical Safety for Medical Systems  
BS EN 60601-1-2 EMC for Medical Devices  
BS EN 301489-1 Electromagnetic Radio Spectrum Matters  
BS EN 301489-3 Electromagnetic Radio Spectrum Matters  
BS EN 300220-1 Electromagnetic Radio Spectrum Matters Short Range Devices  
BS EN 300220-3 Electromagnetic Radio Spectrum Matters Short Range Devices

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed \_\_\_\_\_ Authorised Management Representative

Name Mr M Dines

Date 11 August 2009

Being a duly authorised officer of the Company

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