

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** CE 547117  
**Issued To:** Cleveland Medical Devices Inc.  
4415 Euclid Avenue  
Cleveland  
Ohio  
44103  
USA

In respect of:

**The manufacture of portable, wireless, patient monitoring devices for sleep disorders and associated accessories.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Gary Fenton, Global Assurance Director

First Issued: **16 October 2009**

Date: **07 October 2014**

Expiry Date: **15 October 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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4415 Euclid Avenue  
Cleveland  
Ohio  
44103  
USA**

**Subcontractor:**

**Service(s) supplied**

Emergo Europe  
Molenstraat 15  
2513 BH The Hague  
Netherlands

**EU Representative**

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 547117**  
 Date: **07 October 2014**  
 Issued To: **Cleveland Medical Devices Inc.  
 4415 Euclid Avenue  
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 Ohio  
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 USA**

Date	Reference Number	Action
16 October 2009	7325103	First issue
07 October 2014	8153942	Certificate renewal and removal of patient monitoring devices for movement disorders from scope and extension of scope to include associated accessories.

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