

EC Certificate - Product Quality Assurance

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

No. CE 85248
Issued To: **Human Factors Research Unit
Institute of Sound & Vibration Research
Building 19
University of Southampton
Highfield
Southampton
SO17 1BJ
United Kingdom**

In respect of:

The final inspection and test of neuro sensory perception measurement devices including thermal aesthesiometers and vibration perception meters; and vascular performance measurement devices including multi-channel plethysmographs.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex VI. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb 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: **04 October 2004**

Date: **10 September 2014**

Expiry Date: **09 September 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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Certificate History

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| Date | Reference Number | Action |
|-------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 04 October 2004 | | First issue |
| 05 October 2009 | 7297134 | Certificate renewal |
| 10 September 2014 | 8164082 | Certificate renewal Change of scope from: The final inspection and test of neuro sensory perception measurement devices including thermal aesthesiometers and vibration perception meters; and vascular performance measurement devices including multi-channel plethysmographs and multi channel temperature monitors. To: The final inspection and test of neuro sensory perception measurement devices including thermal aesthesiometers and vibration perception meters; and vascular performance measurement devices including multi-channel plethysmographs. |