

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

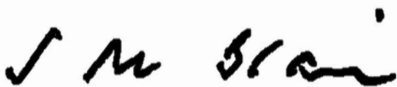
**No.** CE 80325  
Issued To: **LKC Technologies, Inc.**  
**2 Professional Drive**  
**Suite 222**  
**Gaithersburg**  
**Maryland**  
**20879**  
**USA**

In respect of:

**The design, development and manufacture of Visual Electrodiagnostic Equipment**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2004-01-16**

Date: **2019-01-15**

Expiry Date: **2024-01-15**

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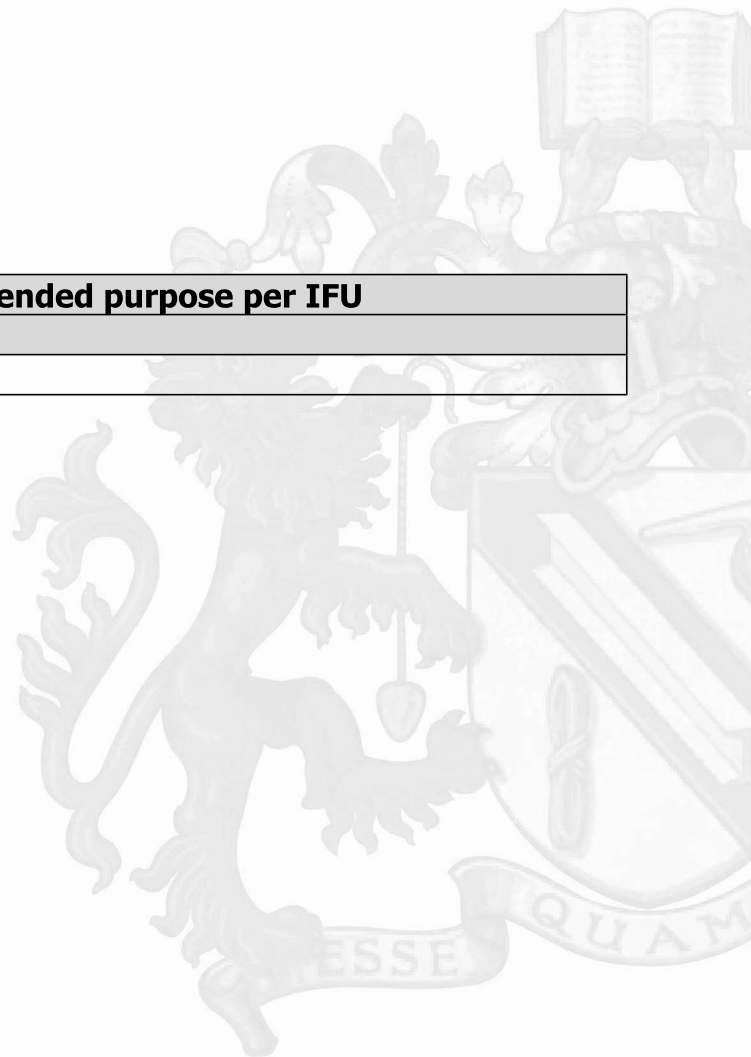
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## Supplementary Information to CE 80325

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1105	Electroretinograph	N/A



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## List of Significant Subcontractors

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

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**Subcontractor:**

Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**Service(s) supplied**

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 80325**  
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 Maryland  
 20879  
 USA**

Date	Reference Number	Action
16 January 2004		Original issue. EC certification transferred from GMED (EC certificate No 0568/B2P3/1)
15 January 2009	7072736	Certificate renewal. Addition of EU Representative as a significant sub-contractor: Emergo Europe. Minor correction to wording of scope to remove the word 'For'
02 December 2013	8081354	Certificate renewal.
Current	9689411	Certificate renewal. Change of address for the EU Representation: Emergo Europe. Added product table.