By Royal Charter

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 2797):

Albert Roossien, Regulatory Lead

First Issued: **2004-01-16** Date: **2019-03-08** Expiry Date: **2024-01-15**

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Supplementary Information to CE 80325

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

First Issued: **2004-01-16** Date: **2019-03-08** Expiry Date: **2024-01-15**

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List of Significant Subcontractors

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

Certificate No:	**CE 80325**
Date:	**2019-03-08**
Issued To:	**LKC Technologies, Inc.** **2 Professional Drive** **Suite 222** **Gaithersburg** **Maryland** **20879** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 80325**
Date: **2019-03-08**
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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.
15 January 2019	9689411	Certificate renewal. Change of address for the EU Representation: Emergo Europe. Added product table.
Current	7781709	Traceable to NB 0086.