

# EC Certificate - Full Quality Assurance System

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

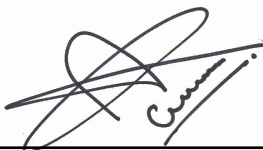
**No.** CE 80325  
**Issued To:** LKC Technologies, Inc.  
2 Professional Drive  
Suite 222  
Gaithersburg  
Maryland  
20879  
USA

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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Page 1 of 2

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

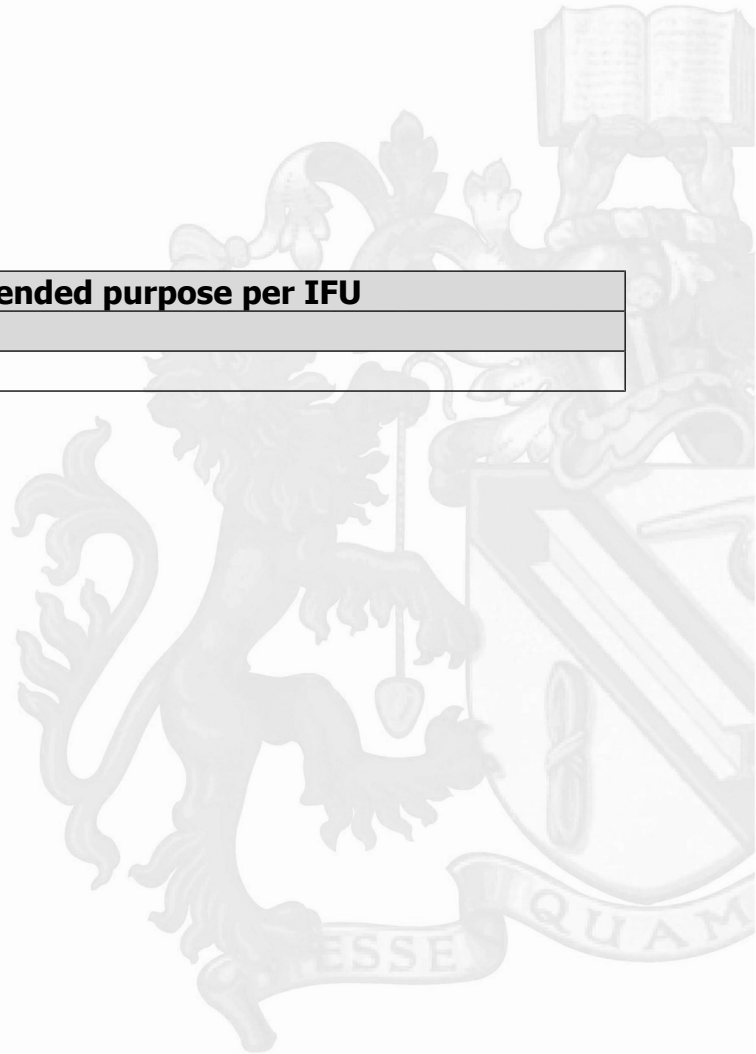
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## Supplementary Information to CE 80325

Issued To:

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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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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**  
 Issued To: **LKC Technologies, Inc.  
 2 Professional Drive  
 Suite 222  
 Gaithersburg  
 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.
15 January 2019	9689411	Certificate renewal. Change of address for the EU Representation: Emergo Europe. Added product table.
Current	7781709	Traceable to NB 0086.

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