

# EC Certificate - Production Quality Assurance

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

**No.** CE 523007  
**Issued To:** **Lincoln Diagnostics, Inc.**  
**240 East Hickory Point Road**  
**Decatur**  
**Illinois**  
**62526**  
**USA**

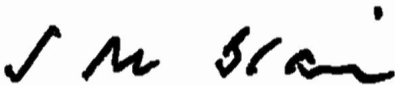
In respect of:

**The manufacture of sterile single use allergy skin test devices.**

**Those aspects of Annex V concerned with securing and maintaining sterile conditions of the following allergy skin test devices: wells, trays, and stems**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2007-10-09**

Date: **2017-10-06**

Expiry Date: **2022-10-08**

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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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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Emergo Europe B.V. Prinsessegracht 20 2514 AP The Hague The Netherlands	<b>EU Representative</b>
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	<b>Gamma Sterilization</b>
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	<b>ETO Sterilization</b>

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# EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
09 October 2007		First issue.
05 October 2012	7906905	Certificate renewal Addition of Diagon Ltd as a significant subcontractor and administrative update to certificate format.
Current	8749690	Certificate Renewal. Scope clarification to identify Class Is devices. Change of EU Rep from Diagon Ltd to Emergo Europe. Administrative update to name and address of significant subcontractor Sterigenics US, LLC. Administrative update to name of significant subcontractor STERIS Isomedix.