By Royal Charter

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2007-10-09** Date: **2019-09-09** Expiry Date: **2022-10-08**

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Supplementary Information to CE 523007

Issued To:

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NBOG code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD0106 MDS7006	Single use allergy skin test devices	Not applicable for Class IIa
Class Is		
MDS 7006	Allergy skin test devices: wells, trays and stems	Not applicable for Class Is

First Issued: **2007-10-09** Date: **2019-09-09** Expiry Date: **2022-10-08**

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List of Significant Subcontractors

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

Certificate No:	**CE 523007**
Date:	**2019-09-09**
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Subcontractor:	**Service(s) supplied**
Emergo Europe B.V Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	**Gamma Sterilization**
Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 523007**

Date: **2019-09-09**

Issued To: **Lincoln Diagnostics, Inc.**
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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.
06 October 2017	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.
25 February 2019	7781285	Traceable to NB 0086
Current	9755893	Addition of subcontractor Midwest Sterilization Corporation. Removal of subcontractor Sterigenics