

Production Quality Assurance

No. CE 523007



Issued to:

Lincoln Diagnostics, Inc.
240 East Hickory Point Road
Decatur
Illinois
62526
USA

In respect of:

The manufacture of disposable allergy skin test devices

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

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

A handwritten signature in black ink, appearing to be 'Gary Fenton', written over a horizontal line.

Gary Fenton, Global Assurance Director

First Issued: **9 Oct 2007**

Date: **5 Oct 2012**

Expiration Date: **8 Oct 2017**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

*raising standards worldwide*TM



List of Significant Subcontractors

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

Certificate No. **CE 523007**
Date: **5 Oct 2012**
Issued to: **Lincoln Diagnostics, Inc.**
Decatur
USA

Subcontractor	Service(s) supplied
Diagon Ltd. H-1047 Budapest Baross u. 52. Hungary	EU Representative
Sterigenics 7775 South Quincy Street Willowbrook IL 60521 USA	ETO Sterilization
STERIS Isomedix Services, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	Gamma Sterilization

History of Quality Assurance Certificate

Certificate No: CE 523007
Issue Date: 5 Oct 2012
Issued to: Lincoln Diagnostics, Inc.
Decatur
USA

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