

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F003202

Holds Certificate No:

MDSAP 703465

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, manufacture, and distribution of sterile disposable allergy skin test devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-08-19

Effective Date: 2023-06-29

Expiry Date: 2026-06-28



BSI Group America Inc. is an MDSAP recognised auditing organization

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