

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Helena Laboratories, Corp.
1530 Lindbergh Drive
Beaumont
Texas
77704-0752
USA

Facility ID Number: F005096

Holds Certificate No:

MDSAP 734359

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, service and installation of equipment and consumables for in-vitro diagnostic use primarily in the areas of electrophoresis, hemostasis, occult blood testing and other in-vitro tests and equipment.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-03-03

Effective Date: 2021-03-03

Expiry Date: 2024-03-02



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 734359**

Location

Helena Laboratories, Corp.
1530 Lindbergh Drive
Beaumont
Texas
77704-0752
USA
Facility ID Number: F005096

Registered Activities

The design, manufacture, service and installation of reagents and consumables for in-vitro diagnostic use primarily in the areas of electrophoresis, hemostasis, occult blood testing and other in-vitro tests and equipment.

Helena Laboratories, Corp.
3795 Washington Blvd.
Beaumont
Texas
77705
USA
Facility ID Number: F005097

The design, manufacture, service and installation of equipment and software for in-vitro diagnostic use primarily in the areas of electrophoresis, hemostasis, occult blood testing and other in-vitro tests and equipment.



Original Registration Date: 2021-03-03

Effective Date: 2021-03-03

Expiry Date: 2024-03-02

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.