

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

Holds Certificate No:

FM 72333

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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: 2002-12-20

Latest Revision Date: 2021-01-06

Effective Date: 2021-03-29

Expiry Date: 2024-03-28

Page: 1 of 2



...making excellence a habit.™

Certificate No: **FM 72333**

Location

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

Registered Activities

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.

Helena Laboratories, Corp.
3795 Washington Blvd.
Beaumont
Texas
77705
USA

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.



Original Registration Date: 2002-12-20

Latest Revision Date: 2021-01-06

Effective Date: 2021-03-29

Expiry Date: 2024-03-28

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). 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.