

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2003

This is to certify that: Helena Laboratories, Inc.
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 13485:2003 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, column chromatography, occult blood testing and other in-vitro tests and equipment.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 12/20/2002 Effective Date: 04/10/2015 Expiry date: 04/09/2018



**CMDCAS
Recognized
Registrar**

Certificate No:

FM 72333

Location	Registered Activities
Helena Laboratories, Inc. 1530 Lindbergh Drive Beaumont Texas 77704-0752 USA	The design, manufacture, service and installation of equipment and consumables for in-vitro diagnostic use primarily in the areas of electrophoresis, hemostasis, column chromatography, occult blood testing and other in-vitro tests and equipment.
Helena Laboratories, Inc. 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, column chromatography, occult blood testing and other in-vitro tests and equipment.



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