

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Helena Laboratories, Inc.
1530 Lindbergh Dr.
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, sterile incision devices and other in-vitro tests and equipment.

The above scope of registration includes activities at:
Helena Laboratories
3795 Washington Blvd.
Beaumont, TX. 77704-0752

For and on behalf of BSI:



President, BSI Management Systems America, Inc.

Originally Registered: **12/20/2002**

Effective Date: **04/30/2009**

Expiry Date: **04/29/2012**



**CMDCAS
Recognized
Registrar**

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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](#). 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: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.