By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Helena Laboratories, Corp.
1530 Lindbergh Drive
Beaumont
Texas
77707
USA

Holds Certificate Number: FM 72333

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

The design and development, manufacture, and distribution of in vitro diagnostic reagents, assay kits, calibrators, and controls for the qualitative and quantitative analysis of analytes in human biological specimens, including but not limited to blood, urine, and cerebrospinal fluid, for use in professional healthcare and laboratory settings, including near-patient/point-of-care environments.

The design and development, manufacture, installation, servicing and distribution of in vitro diagnostic analyzers and associated software for the qualitative and quantitative analysis of analytes in human biological specimens, for use in professional healthcare and laboratory settings, including near-patient/point-of-care environments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2002-12-20
Latest Revision Date: 2026-09-29

Effective Date: 2024-03-03
Expiry Date: 2027-03-02

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.
America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.

Certificate No: FM 72333

Location	Registered Activities
Helena Laboratories, Corp. 1530 Lindbergh Drive Beaumont Texas 77707 USA	The design and development, manufacture, and distribution of in vitro diagnostic reagents, assay kits, calibrators, and controls for the qualitative and quantitative analysis of analytes in human biological specimens, including but not limited to blood, urine, and cerebrospinal fluid, for use in professional healthcare and laboratory settings, including near-patient/point-of-care environments.
Helena Laboratories, Corp. 3795 Washington Blvd. Beaumont Texas 77705 USA	The design and development, manufacture, installation, servicing and distribution of in vitro diagnostic analyzers and associated software for the qualitative and quantitative analysis of analytes in human biological specimens, for use in professional healthcare and laboratory settings, including near-patient/point-of-care environments.

Original Registration Date: 2002-12-20

Latest Revision Date: 2026-09-29

Effective Date: 2024-03-03

Expiry Date: 2027-03-02

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.
America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.