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, and manufacture of in-vitro diagnostic reagents and test kits used in the diagnosis, management, and/or detection of blood analytes, blood components, cancer, cardiac markers, coagulation, and disease status, including near patient/point of care in-vitro diagnostic medical devices used.

The design and development, manufacture, installation, and servicing of in-vitro diagnostic analyzers/software used in the diagnosis, management, and/or detection of blood analytes, blood components, cancer, cardiac markers, coagulation, and disease status, including near patient/point of care in-vitro diagnostic medical devices used.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-12-20
Latest Revision Date: 2024-02-27

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

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Certificate No: FM 72333

Location	Registered Activities
Helena Laboratories, Corp. 1530 Lindbergh Drive Beaumont Texas 77707 USA	The design and development, and manufacture of in-vitro diagnostic reagents and test kits used in the diagnosis, management, and/or detection of blood analytes, blood components, cancer, cardiac markers, coagulation, and disease status, including near patient/point of care in-vitro diagnostic medical devices used.
Helena Laboratories, Corp. 3795 Washington Blvd. Beaumont Texas 77705 USA	The design and development, manufacture, installation, and servicing of in-vitro diagnostic analyzers/software used in the diagnosis, management, and/or detection of blood analytes, blood components, cancer, cardiac markers, coagulation, and disease status, including near patient/point of care in-vitro diagnostic medical devices used.

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