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

Facility ID Number: F005096

Holds Certificate No: **MDSAP 734359**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-03-03 Effective Date: 2024-03-03 Expiry Date: 2027-03-02

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 734359**

Registered 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.

Original Registration Date: 2021-03-03 Effective Date: 2024-03-03 Expiry Date: 2027-03-02

Certificate No: **MDSAP 734359**

Location	Registered Activities
Helena Laboratories, Corp. 1530 Lindbergh Drive Beaumont Texas 77707 USA Facility ID Number: F005096	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 Facility ID Number: F005097	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.

Original Registration Date: 2021-03-03 Effective Date: 2024-03-03 Expiry Date: 2027-03-02