

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis
Minnesota
55413
USA

Facility ID Number: F000370

Holds Certificate No:

MDSAP 654945

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. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, and distribution of in-vitro diagnostic antibodies and proteins, Hematology Controls, Calibrators and linearity products for use in in-vitro diagnostic medical devices. The design and development, manufacture, and distribution of In-Vitro Diagnostic ELISA Kits and Controls for screening, monitoring and diagnosis of diseases and conditions.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-04-27

Effective Date: 2022-09-18

Expiry Date: 2025-09-17



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

...making excellence a habit.™

Certificate No: **MDSAP 654945**

Location

R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis
Minnesota
55413
USA
Facility ID Number: F000370

Registered Activities

Design, Manufacture and Distribution of Hematology Controls, Calibrators, and Linearity Products; ELISA In-Vitro Diagnostic Kits and Controls; Antibodies and Proteins for Use in the Medical Device Industry.

R&D Systems, Inc.
22 Empire Drive
Saint Paul
Minnesota
55103
USA
Facility ID Number: F000370

The design and development, manufacture, and distribution of in-vitro diagnostic antibodies and proteins, Hematology Controls, Calibrators and linearity products for use in in-vitro diagnostic medical devices. The design and development, manufacture, and distribution of In-Vitro Diagnostic ELISA Kits and Controls for screening, monitoring and diagnosis of diseases and conditions.



Original Registration Date: 2018-04-27

Effective Date: 2022-09-18

Expiry Date: 2025-09-17

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). 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: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.