

# 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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-04-27

Effective Date: 2022-10-06

Expiry Date: 2025-09-17



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 654945**

## Registered Scope:

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: 2022-10-06

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Page: 2 of 3

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](http://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.

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

Manufacture of Proteins for Use in the Medical Device Industry.



Original Registration Date: 2018-04-27

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Page: 3 of 3

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