

# 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

Holds Certificate Number: **FM 547846**

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

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.

For and on behalf of BSI:

\_\_\_\_\_  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-03-27

Latest Revision Date: 2022-09-16

Effective Date: 2022-09-18

Expiry Date: 2025-09-17

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 547846

Location	Registered Activities
R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis Minnesota 55413 USA	Design, Manufacture, and Distribution of Hematology Controls and Calibrators; Design and Manufacture of ELISA In-Vitro Diagnostic Kits and Controls for Iron Deficiency Anemia, Polycythemia, and Vitamin D status; Design and Distribution of Antibodies and Proteins for Use in the Medical Device Industry.
R&D Systems, Inc. 22 Empire Drive Saint Paul Minnesota 55103 USA	Manufacture of Proteins for Use in the Medical Device Industry.



Original Registration Date: 2009-03-27

Latest Revision Date: 2022-09-16

Effective Date: 2022-09-18

Expiry Date: 2025-09-17

Page: 2 of 2

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](http://www.bsigroup.com/ClientDirectory)

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.  
Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.