

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 Global Regulatory & Quality

Original Registration Date: 2009-03-27

Latest Revision Date: 2025-09-09

Effective Date: 2025-09-18

Expiry Date: 2028-09-17

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...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, and Polycythemia; 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.



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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

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