

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 No:

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:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2009-03-27

Latest Revision Date: 2019-08-06

Effective Date: 2019-09-18

Expiry Date: 2022-09-17

Page: 1 of 1



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