

# 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

DUNS Number: 08-724-8183

Holds Certificate No:

**MDSAP 654945**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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

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: 2018-04-27

Effective Date: 2019-09-18

Expiry Date: 2022-09-17



BSI Group America Inc. is an MDSAP authorized auditing organization

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