



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 [if design controls are part of the certification]; 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; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; 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:

Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-04-27

Effective Date: 2018-04-27

Expiry date: 2019-09-17



BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

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