bsi.

By Royal Charter

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

Facility ID Number: F000370

Holds Certificate No: **MDSAP 654945**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
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

The design and development, manufacture, and distribution of invitro diagnostic Hematology Controls, Calibrators and linearity products for use in in-vitro diagnostic medical devices. The design and development, manufacture, and distribution of In-Vitro Diagnostic ELISA Kits and Controls for screening, monitoring and diagnosis of diseases and conditions.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-04-27 Effective Date: 2024-06-12 Expiry Date: 2025-09-17

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™