



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

R2 Diagnostics, Inc.

1801 Commerce Drive South Bend Indiana 46628 USA

Holds Certificate Number:

FM 87007

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture of in vitro diagnostic devices and test kits used in the diagnosis, management and detection of coagulation.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2004-09-29 Latest Revision Date: 2025-01-08 Effective Date: 2025-02-01 Expiry Date: 2028-01-31

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...making excellence a habit."

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 <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780 BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V. Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA