



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 No:

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.

ian CS ada

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-09-29 Latest Revision Date: 2022-01-04





Effective Date: 2022-02-01 Expiry Date: 2025-01-31

Page: 1 of 1

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.