

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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