

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

The design, development, manufacture and distribution of products for the diagnostic hemostasis market.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 09/29/2004

Effective Date: 02/01/2016

Expiry Date: 01/31/2019



CMDCAS
Recognized
Registrar



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