

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Fortress Diagnostics
Unit 2C Antrim Technology Park
Belfast Road
Antrim
BT41 1QS
United Kingdom

Holds Certificate Number: MD 660481

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development and manufacture of in vitro diagnostic medical device kits, reagents, controls and instrumentation including immunoassay, clinical chemistry, point of care, haemostasis and serology.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 14/01/2017

Latest Revision Date: 14/01/2017

Effective Date: 14/01/2017

Expiry Date: 28/02/2019

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