

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Radox Laboratories Limited  
55 Diamond Road  
Crumlin  
County Antrim  
BT29 4QY  
United Kingdom

Holds Certificate Number:

**MD 686778**

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

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-03-19

Latest Revision Date: 2018-08-07

Effective Date: 2018-08-19

Expiry Date: 2021-08-18

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...making excellence a habit.™

Certificate No: **MD 686778**

Location	Registered Activities
Radox Laboratories Limited 55 Diamond Road Crumlin County Antrim BT29 4QY United Kingdom	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Radox Laboratories Limited 34 Diamond Road Crumlin County Antrim BT29 4QX United Kingdom	The design, development and manufacture of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Radox Laboratories Limited 36 Largy Road Crumlin County Antrim BT29 2RN United Kingdom	The design, development, manufacture, service and distribution of in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Radox Laboratories Limited 44 Largy Road Crumlin County Antrim BT29 4RN United Kingdom	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls and in-vitro diagnosis analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

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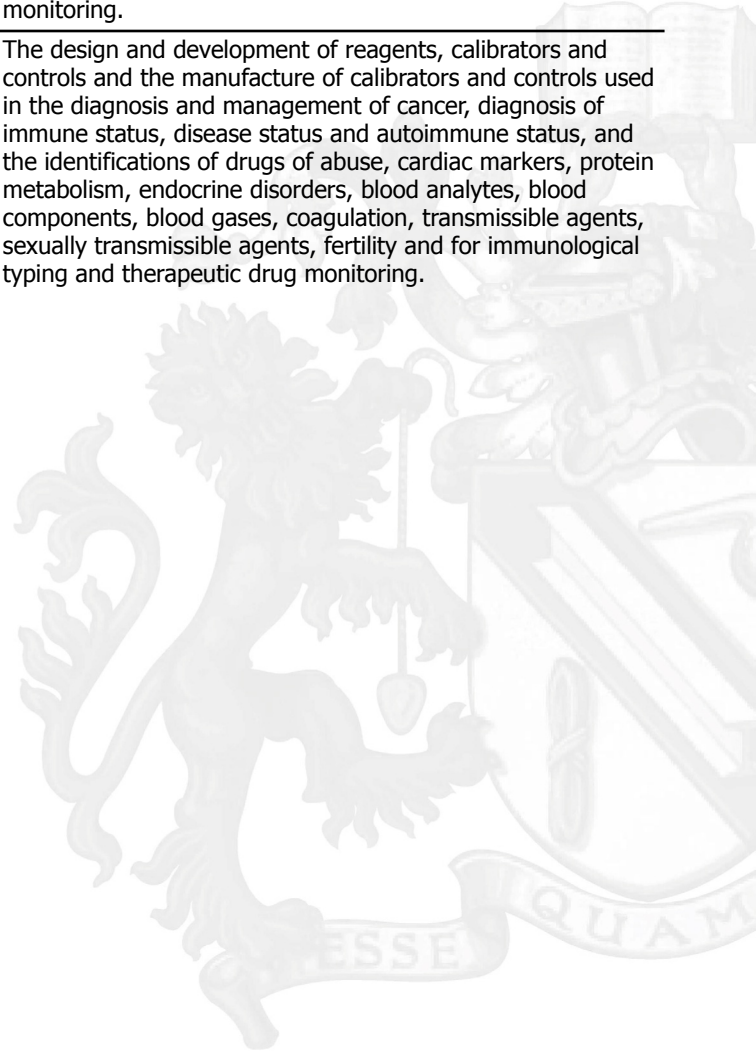
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Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Certificate No: **MD 686778**

Location	Registered Activities
Randox Teoranta Meenmore Dungloe Donegal F94 TV06 Ireland	The design, development, manufacture and distribution of in-vitro diagnostic analysers, manufacture of in-vitro diagnostic reagents, used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.
Randox Laboratories Limited 30 Randalstown Rd Antrim BT41 4FL United Kingdom	The design and development of reagents, calibrators and controls and the manufacture of calibrators and controls used in the diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identifications of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.



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