

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Randox Laboratories Limited**  
55 Diamond Road  
Crumlin  
County Antrim  
BT29 4QY  
United Kingdom

DUNS Number: 21-861-0724

Holds Certificate No: **MDSAP 699499**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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: 2019-11-06

Effective Date: 2019-11-06

Expiry Date: 2022-11-05



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 3

...making excellence a habit.™

Certificate No: **MDSAP 699499**

Location	Registered Activities
Randox Laboratories Limited 55 Diamond Road Crumlin County Antrim BT29 4QY United Kingdom DUNS Number: 21-861-0724	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.
Randox 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.
Randox 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.
Randox 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.

Original Registration Date: 2019-11-06

Effective Date: 2019-11-06

Expiry Date: 2022-11-05

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

To be read in conjunction with the scope above or the attached appendix.

Certificate No: **MDSAP 699499**

Location	Registered Activities
Radox Teoranta Meenmore Dungloe Donegal F94 TV06 Ireland DUNS Number: 89-697-6409	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.
Radox Science Park 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.
Radox Laboratories Ltd 61 Largy Road Crumlin County Antrim BT29 4RR 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, cardiac markers, protein metabolism, endocrine disorders, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

Original Registration Date: 2019-11-06

Effective Date: 2019-11-06

Expiry Date: 2022-11-05

Page: 3 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.