By Royal Charter

Certificate of Registration

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

This is to certify that:

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg
New Jersey
08876
USA

Holds Certificate Number: MD 739945

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

Design, Manufacture, and Distribution of In Vitro Diagnostic Kits, integrated systems and associated software used in the diagnosis and management of disease status of infectious diseases, donor screening associated with infectious diseases, primary screening associated with oncogenic viruses, detection of biomarkers for companion diagnostics, microbiology, and genetic testing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-03-05
Latest Revision Date: 2025-11-21

Effective Date: 2024-07-01
Expiry Date: 2027-06-30

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Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: MD 739945

Location	Registered Activities
Roche Molecular Systems, Inc. 1080 US Highway 202 South Branchburg New Jersey 08876 USA	Design, manufacture, packaging, warehouse, and distribution of In Vitro Diagnostic Kits, integrated systems and associated software used in the diagnosis and management of disease status of infectious diseases, donor screening associated with infectious diseases, primary screening associated with oncogenic viruses, detection of biomarkers for companion diagnostics, microbiology, and genetic testing.
Roche Molecular Systems, Inc. 2 Millennium Way Branchburg New Jersey 08876 USA	Warehouse and distribution
Roche Molecular Systems, Inc 4300 Hacienda Drive Pleasanton California 94588 USA	Design and Development.

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