



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Illumina, Inc.** 5200 Illumina Way San Diego California 92122 USA

Holds Certificate Number:

FM 565017

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

Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-01-14 Latest Revision Date: 2023-08-07 Effective Date: 2022-12-06 Expiry Date: 2025-12-05

Page: 1 of 2



...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V. Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

## Certificate No: FM 565017

Location

Illumina, Inc. Manufacture and process development of components used 524 Genomic Drive in reagents for sequencing, genotyping and gene expression products used for genetic analysis. Madison Wisconsin 53719 USA Illumina, Inc. Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression 5200 Illumina Way and PCR - products, instruments and software - used for San Diego genetic analysis. California 92122 USA Illumina, Inc. Manufacturing and distribution of instruments used for genetic analysis. Hayward 25861 Industrial Blvd. Hayward California 94545 USA Installation, servicing, technical, product and laboratory Illumina Cambridge Limited (Cambridge) support services for Sequencing, Genotyping, Gene 19 Granta Park Expression (products, instruments and software) used for Great Abington genetic analysis. Purchasing, planning, procurement and CB21 6DF supply chain management. Provision of technical services for United Kingdom customers and internal technical staff in use of instruments and systems. Regional regulatory support. Design and development of clinical software and assays for genetic analysis.

**Registered Activities** 

Original Registration Date: 2011-01-14 Latest Revision Date: 2023-08-07 Effective Date: 2022-12-06 Expiry Date: 2025-12-05

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V. Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.