



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 Effective Date: 2022-12-06 Latest Revision Date: 2022-11-22 Expiry Date: 2025-12-05

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...making excellence a habit."





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Certificate No: FM 565017

Location	Registered Activities
Illumina, Inc. 524 Genomic Drive Madison Wisconsin 53719 USA	Manufacture and process development of components used in reagents for sequencing, genotyping and gene expression products used for genetic analysis.
Illumina, Inc. 5200 Illumina Way San Diego California 92122 USA	Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.
Illumina, Inc. Hayward 25861 Industrial Blvd. Hayward California 94545 USA	Manufacturing and distribution of instruments used for genetic analysis.
Illumina, Inc. 200 Lincoln Centre Drive Foster City California 94404 USA	Design and development of software and assays.
Illumina Cambridge Limited (Cambridge) 19 Granta Park Great Abington CB21 6DF United Kingdom	Installation, servicing, technical, product and laboratory support services for Sequencing, Genotyping, Gene Expression (products, instruments and software) used for genetic analysis. Purchasing, planning, procurement and supply chain management. Provision of technical services for customers and internal technical staff in use of instruments

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and systems. Regional regulatory support.

genetic analysis.

Design and development of clinical software and assays for

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