By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F000219

Holds Certificate No: **MDSAP 660264**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-12-06 Effective Date: 2025-12-06 Expiry Date: 2028-12-05

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 660264**

Registered Scope:

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

Original Registration Date: 2016-12-06 Effective Date: 2025-12-06 Expiry Date: 2028-12-05

Certificate No: **MDSAP 660264**

Location	Registered Activities
Illumina, Inc. 5200 Illumina Way San Diego California 92122 USA Facility ID Number: F000219	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 Facility ID Number: F001879	Manufacturing and distribution of instruments used for genetic analysis.

Original Registration Date: 2016-12-06 Effective Date: 2025-12-06 Expiry Date: 2028-12-05