

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that: **Illumina, Inc.**
5200 Illumina Way
San Diego
California
92122
USA

DUNS Number: 03-330-5264

Holds certificate No: **MDSAP 660264**

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 [if design controls are part of the certification]; 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; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

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:



Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2016-12-06

Effective Date: 2018-07-27

Expiry date: 2019-12-05



BSI Group America Inc. is an MDSAP authorized auditing organization

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Location	Registered Activities
ILLUMINA, INC. 5200 ILLUMINA WAY SAN DIEGO CALIFORNIA 92122 USA DUNS Number: 03-330-5264	Manufacture and Distribution of in-vitro diagnostic products (reagents and product software) used for genetic analysis.
ILLUMINA 9440 CARROLL PARK DRIVE SUITE 100 SAN DIEGO CALIFORNIA 92121 USA DUNS Number: 12-284-2844	Manufacture and Distribution of in-vitro diagnostic products (reagents) used for genetic analysis.
ILLUMINA, INC. HAYWARD 25861 INDUSTRIAL BLVD. HAYWARD CALIFORNIA 94545 USA DUNS Number: 80-313-0991	Manufacturing and distribution of instruments used for genetic analysis.

Original Registration Date: 2016-12-06

Effective Date: 2018-07-27

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This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.