



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

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...making excellence a habit."



To be read in conjunction with the scope above or the attached appendix.

This certificate remains the property of BSI and shall be returned immediately upon request.

MDSAP 660264 Certificate No:

Location	Registered Activities
Illumina, Inc.	Manufacture and Distribution of in-vitro diagnostic products
5200 Illumina Way	(reagents and product software) used for genetic analysis.
San Diego	
California	
92122	
USA	
DUNS Number: 03-330-5264	
Illumina	Manufacture and Distribution of in-vitro diagnostic products
9440 Carroll Park Drive	(reagents) used for genetic analysis.
Suite 100	
San Diego	
California	
92121	
USA	
DUNS Number: 12-284-2844	
Illumina, Inc.	Manufacturing and distribution of instruments used for genetic
Hayward	analysis.

25861 Industrial Blvd. Hayward

California 94545

USA

DUNS Number: 80-313-0991

Original Registration Date: 2016-12-06 Effective Date: 2018-07-27 Expiry date: 2019-12-05

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