

# 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 Medical Devices

Original Registration Date: 2016-12-06

Effective Date: 2024-01-18

Expiry Date: 2025-12-05



BSI Group America Inc. is an MDSAP recognised auditing organization

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...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: 2024-01-18

Expiry Date: 2025-12-05

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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

Certificate No: **MDSAP 660264**

Location

ILLUMINA, INC.  
5200 ILLUMINA WAY  
SAN DIEGO  
CALIFORNIA  
92122  
USA  
Facility ID Number: F000219

Registered Activities

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: 2024-01-18

Expiry Date: 2025-12-05

Page: 3 of 3

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