

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Illumina Singapore Pte Ltd
29 Woodlands Industrial Park E1
Northtech
757716
Singapore

Facility ID Number: F001880

Holds Certificate No:

MDSAP 696226

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

The design and development, manufacture and distribution of in vitro diagnostic kits and instruments for sequencing, genotyping and gene expression used for genetic analysis.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-02-08

Effective Date: 2023-12-01

Expiry Date: 2024-11-20



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 696226**

Location

Illumina Singapore Pte Ltd
29 Woodlands Industrial Park E1
Northtech
757716
Singapore
Facility ID Number: F001880

Illumina Singapore Pte Ltd
7 North Coast Avenue
Level 7
737664
Singapore
Facility ID Number: F001880

Registered Activities

The design and development, manufacture, storage, and distribution of in vitro diagnostic kits and instruments for sequencing, genotyping and gene expression used for genetic analysis.

The design and development of in vitro diagnostic kits and instruments for sequencing, genotyping and gene expression used for genetic analysis.



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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
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.