By Royal Charter

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 Global Regulatory & Quality

Original Registration Date: 2019-02-08 Effective Date: 2024-11-21 Expiry Date: 2027-11-20

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 696226**

Location	Registered Activities
Illumina Singapore Pte Ltd 29 Woodlands Industrial Park E1 Northtech 757716 Singapore Facility ID Number: F001880	The design and development, manufacture, import, storage and distribution of in vitro diagnostic kits and instruments for sequencing, genotyping and gene expression used for genetic analysis.
Illumina Singapore Pte Ltd 7 North Coast Avenue Level 7 737664 Singapore Facility ID Number: F001880	The design and development of in vitro diagnostic kits and instruments for sequencing, genotyping and gene expression used for genetic analysis.

Original Registration Date: 2019-02-08 Effective Date: 2024-11-21 Expiry Date: 2027-11-20