

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Life Technologies Holdings Pte Ltd
Blk 33 Marsiling Industrial Estate Rd 3
#07-06
739256
Singapore

Facility ID Number: F000265

Holds Certificate No:

MDSAP 696240

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, manufacture, distribution and servicing of in-vitro diagnostic medical devices with associated software and consumables used in the detection of genetic changes that may lead to disease presence or susceptibility. Distribution includes storage and import.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-01-24

Effective Date: 2024-11-08

Expiry Date: 2027-11-07



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 696240**

Location	Registered Activities
Life Technologies Holdings Pte Ltd Blk 33 Marsiling Industrial Estate Rd 3 #07-06 739256 Singapore Facility ID Number: F000265	The design, manufacture, distribution and servicing of in-vitro diagnostic medical devices with associated genetic software and consumables used in the detection of genetic changes that may lead to disease presence or susceptibility. Distribution includes storage and import. System Integrator (The design, manufacture, distribution and service of invitro diagnostic medical devices with associated software and consumables used in the detection of genetic changes that may lead to disease presence or susceptibility). Distribution includes storage and import.
Life Technologies Holdings Pte Ltd No. 2 Tuas View Place, #02-06 Enterprise Logistics Centre 637431 Singapore Facility ID Number: F000265	The design, manufacture, distribution and servicing of in-vitro diagnostic medical devices with associated genetic software and consumables used in the detection of genetic changes that may lead to disease presence or susceptibility. Distribution includes storage and import. System Integrator (The design, manufacture, distribution and service of invitro diagnostic medical devices with associated software and consumables used in the detection of genetic changes that may lead to disease presence or susceptibility). Distribution includes storage and import.
Life Technologies Holdings Pte Ltd Blk 33 Marsiling Industrial Estate Rd 3 Level 2 and Level 5 739256 Singapore Facility ID Number: F000265	The manufacture of in-vitro diagnostics medical devices.
Life Technologies Holdings Pte Ltd Blk 35 Marsiling Industrial Estate Rd 3 #02-04/05 739257 Singapore Facility ID Number: F000265	The design of in-vitro diagnostic medical devices with associated software and consumables used in detection of genetic changes that may lead to disease presence or susceptibility.

Original Registration Date: 2019-01-24

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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](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

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