

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
Singapore 739256

DUNS Number: 62-854-8377

Holds certificate No:

MDSAP 696240

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

Please see scope page.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-01-24

Effective Date: 2019-02-15

Expiry date: 2021-11-07

Page: 1 of 3

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BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No:

MDSAP 696240

Registered Scope:

The design, manufacture, import, distribution and service 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.

System Integrator (The design, manufacture, import, distribution and service 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).



Original Registration Date: 2019-01-24

Effective Date: 2019-02-15

Expiry date: 2021-11-07

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: 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 696240**

Location	Registered Activities
Life Technologies Holdings Pte Ltd Blk 33 Marsiling Industrial Estate Rd 3 #07-06 Singapore 739256 DUNS Number: 62-854-8377	The design, manufacture, import, distribution and service 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. System Integrator (The design, manufacture, import, distribution and service 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).
Life Technologies Holdings Pte Ltd No. 2 Tuas View Place, #02-06 Enterprise Logistics Centre Singapore 637431 DUNS Number: 62-854-8377	The design, manufacture, import, distribution and service 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. System Integrator (The design, manufacture, import, distribution and service 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).
Life Technologies Holdings Pte Ltd Blk 33 Marsiling Industrial Estate Rd 3 Level 2 and Level 5 Singapore 739256 DUNS Number: 62-854-8377	The manufacture of in-vitro diagnostics medical devices.

Original Registration Date: 2019-01-24

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Page: 3 of 3

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