



America

CERTIFICATE

No. QS6 084041 0005 Rev. 00

Certificate Holder:

Life Technologies Corporation
Also trading as Invitrogen Corporation
7335 Executive Way
Frederick MD 21704
USA

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

TGA Australia, Health Canada, Brazil ANVISA, USA FDA,
MHLW/PMDA.

See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

08-013-1636

Effective Date:

2018-12-06

Expiry Date:

2021-12-05

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Date of Issue: 2018-12-28

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Overall Scope Statement:

Design, Development and Manufacture of Molecular Biological Buffers and Reagents including Enzymes, Primers, Fluorescent Dyes, Nucleic Acid Purification Products, PCR Related Components, Antibodies and Diagnostic Test Kits used for Research Use Only (RUO), General Purpose Reagent (GPR), Analyte Specific Reagent (ASR), In-Vitro Diagnostic (IVD) Applications, Recombinant Proteins, Growth Factors, and Ancillary Reagents; Warehousing and Distribution of Oligonucleotides and Molecular Biology Kits and Reagents; and Biological Discovery Products including Functional Genomics, Proteomics, Bioinformatics and Cell Biology; and Analytical Instrument Systems



(Arie Henkin)
Manager, Certification Body MHS

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CERTIFICATE

No. QS6 084041 0005 Rev. 00

Facility(ies):

- Life Technologies Corporation Also trading as Invitrogen Corporation
7335 Executive Way, Frederick MD 21704, USA
- Life Technologies Corporation
7302 Governors Way, Frederick MD 21704, USA
- Life Technologies Corporation
6433 English Muffin Way, Fredrick MD 21704, USA
- Life Technologies Corporation
7305 Executive Way, Fredrick MD 21704, USA
- Life Technologies, Corp.
5781 Van Allen Way, Carlsbad CA 92008, USA

Facility Scopes:

- Life Technologies Corporation**
7335, Executive Way, Frederick, MD, 21704, USA
Design, Development and Manufacture of Molecular Biological Buffers and Reagents Described in the Scope
DUNS No: 08-013-1636
Certificate Holder
- Life Technologies Corporation**
7302, Governors Way, Frederick, MD, 21704, USA
Warehousing, Distribution of Oligonucleotides and Molecular Biology Kits and Reagents; and Biological Discovery Products Described in the Scope
DUNS No: 07-867-1101

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CERTIFICATE

No. QS6 084041 0005 Rev. 00

Life Technologies Corporation

6433, English Muffin Way, Frederick, MD, 21703, USA

Warehousing, Distribution of Oligonucleotides and Molecular Biology Kits and Reagents; and Biological Discovery Products Described in the Scope

DUNS No: 08-112-7937

Life Technologies Corporation

7305, Executive Way, Frederick, MD, 21704, USA

Regulatory Affairs Support and Record Control for the Design, Development and Manufacture of Molecular Biological Buffers and Reagents Described in the Scope

DUNS No: 96-993-1018

Life Technologies Corporation

5781 Van Allen Way, Carlsbad, CA 92008

Design and Development of Molecular Biological Buffers and Regents Described in the Scope

DUNS No: 07-830-3961



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Manager, Certification Body MHS