



America

# CERTIFICATE

No. QS6 084041 0005 Rev. 01

**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):** Australia TGA, Brazil ANVISA, Health Canada, 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 [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

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

**REPs Facility ID:** F002920

**Effective Date:** 2022-02-04

**Expiry Date:** 2024-12-05

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**Date of Issue:** 2022-02-11

( Michael Ogunleye )  
 Manager, US Certification Body,  
 Medical and Health Services

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**Regulatory Requirements:      Audit/Certification Criteria**

**Australia**

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**

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

**Canada**

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

**Japan**

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

**United States**

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

**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 General Purpose Reagent (GPR), Analyte Specific Reagent (ASR), In-Vitro Diagnostic (IVD) Applications, Recombinant Proteins, Growth Factors, and Ancillary Reagents; 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**

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**Facility(ies):**

- Life Technologies Corporation Also trading as Invitrogen Corporation  
7335 Executive Way, Frederick MD 21704, USA
- Life Technologies Corporation  
7305 Executive Way, Fredrick MD 21704, USA
- Life Technologies Corporation  
7302 Governors Way, Frederick MD 21704, USA
- Life Technologies Corporation  
6433 English Muffin Way, Fredrick MD 21703, USA
- Life Technologies, Corp.  
5781 Van Allen Way, Carlsbad CA 92008, USA
- Life Technologies Corporation  
6900 English Muffin Way, Fredrick MD 21703, USA
- Life Technologies Corporation  
4640 New Design Rd, Fredrick MD 21703, USA

**Facility Scopes:**

- Life Technologies Corporation Also trading as Invitrogen Corporation**  
7335 Executive Way, Frederick MD 21704, USA  
Design, Development and Manufacture of Molecular Biological Buffers and Reagents described in the Scope  
REPs Facility ID: F002920
- 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  
REPs Facility ID: F002920

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No. QS6 084041 0005 Rev. 01

**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

REPs Facility ID: F002920

**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

REPs Facility ID: F002920

**Life Technologies, Corp.**

5781 Van Allen Way, Carlsbad CA 92008, USA

Design and Development of Molecular Biological Buffers and Reagents described in the Scope

REPs Facility ID: F002924

**Life Technologies Corporation**

6900 English Muffin Way, Frederick MD 21703, USA

Storage and Distribution of Ambient Finished Goods

REPs Facility ID: F002920

**Life Technologies Corporation**

4640 New Design Rd, Frederick MD 21703, USA

Production Raw Material Storage and Supply

REPs Facility ID: F002920

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