



America

CERTIFICATE

No. QS6 084041 0005 Rev. 04

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, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_084041_0005_Rev.04

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

REPs Facility ID: F002920
Report No.: 72196478
Effective Date: 2024-08-03
Expiry Date: 2027-08-02

Page 1 of 4

Date of Issue: 2024-06-05

(Renee Walker)
 Director, US Certification Body, MHS

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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. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

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 Including Diagnostics Software, 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

Page 2 of 4

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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, Frederick MD 21704, USA

Life Technologies Corporation
 7302 Governors Way, Frederick MD 21704, USA

Life Technologies Corporation
 6433 English Muffin Way, Frederick MD 21703, USA

Life Technologies, Corp.
 5781 Van Allen Way, Carlsbad CA 92008, USA

Life Technologies Corporation
 4640 New Design Rd, Frederick 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, Reagents and Diagnostics Software described in the Scope
 REPs Facility ID: F002920

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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; and Analytical Instrument Systems

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

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

Page 4 of 4

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